S. HRG. 116–48

KEEPING SMALL, PREMIUM CIGAR BUSINESSES ROLLING

FIELD HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

APRIL 5, 2019

Printed for the Committee on Small Business and Entrepreneurship

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KEEPING SMALL, PREMIUM CIGAR BUSINESSES ROLLING

FRIDAY, APRIL 5, 2019

UNITED STATES SENATE,
COMMITTEE ON SMALL BUSINESS
AND ENTREPRENEURSHIP,
Tampa, FL.

The Committee met, pursuant to notice, at 1:00 p.m., in the Performing Arts Building Auditorium, Hillsborough Community College, Ybor City Campus, 1411 East 11th Avenue, Hon. Marco Rubio, Chairman of the Committee, presiding.

Present: Senator Rubio.

Also present: Representatives Bilirakis and Castor.

OPENING STATEMENT OF HON. MARCO RUBIO, CHAIRMAN, A U.S. SENATOR FROM FLORIDA

Chairman RUBIO. I call this hearing to order.

I want to thank our witnesses for being here to discuss an important and an historic industry for the State of Florida and for this part of our state.

Before I do, I want to recognize Dr. Atwater, the President of Hillsborough Community College, and Dr. Ginger Clark, the Ybor campus president. They have been fine to work with, and we appreciate very much all the help they've given us in setting this up today.

As the Chairman of this committee, I'm pleased to bring more awareness to this iconic industry and the regulatory assault that threatens it, and there really is no better location in this state to do it than here in Tampa, in this area known as Cigar City.

Florida's premium cigar industry is one that is rooted in small, family-run businesses. These are businesses that have been handed down generation by generation, and many are representatives of the cultural history of the Cuban community that has made Florida their home way back, even before the current migration, going into the 1800s and in this very part of our state, near Ybor City.

One such example of that is J.C. Newman Cigar Company represented by one of our witnesses, Drew Newman, the founder's great-grandson. The company is a fourth-generation business that has spanned an impressive 124 years. Unfortunately, manufacturers like J.C. Newman, retailers like Corona Cigars, and the rest of the premium cigar industry are under attack.

A 2009 law, and a subsequent final rule by the previous administration, allowed the Food and Drug Administration to regulate the manufacture, import, packaging, labeling, advertisement, pro-

motion, sale, and distribution of premium cigars, a move that was intended to protect children from cigarettes and other tobacco products.

I fully support laws which prohibit minors from smoking and to prevent people from falling into that habit. But tobacco is a legal product, and small manufacturers and retailers of premium cigars are wrongfully being targeted when they were never supposed to be the target of this to begin with. It's simply not right for government to unfairly place detrimental fees and regulations on an entire industry simply because some do not like the product that they are manufacturing.

It must also be noted that the rule, issued in 2016, encompassed tobacco products on the market since 2007, a full two years before the authorizing legislation became law. The regulatory cost of compliance would give preference to foreign-made products and destroy this American industry.

For instance, J.C. Newman sells about $10 million worth of products every year. It would cost them approximately three times that amount just to comply with the proposed regulation. FDA has calculated that 90 percent of the businesses affected by this rule are considered to be small. But think about it, to comply with these regulations it would cost them three times what they make in any given year, and you don't need to be a business major to figure out pretty quickly you cannot survive when the cost of compliance is three times your annual revenue as a company.

This over-regulation, it's not necessary. It's already illegal to sell tobacco products to anyone under the age of 18. In fact, the State of Florida is looking to raise that age in the legislature. First regular use is on average, 24-and-a-half years old. The FDA NIH research was unable to provide any data at all on youth that consumed traditional cigars frequently or daily. This is because, as they said, premium cigars are not made for children, they're not marketed to children, they're not consumed by children. So this begs the question of why premium cigars are wrongly being regulated under a law that's aimed to reduce youth consumption of tobacco if it is not a product that youth are consuming.

So what can we do to stop this overreach? In Congress I have a bill, Senate Bill 9, the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act, which would exempt just this industry from FDA regulations. This legislation, which I introduced on the first day of the Congress, would only apply to the premium cigar industry. It has the bipartisan support of 11 senators.

I am pleased that I'm joined here today by my colleagues Congressman Castor and also Congressman Bilirakis, who led the House effort with 35 bipartisan co-sponsors. For each of the three fiscal years since 2016, when the final rule was finalized, the House of Representatives passed legislation exempting premium cigars from harmful FDA regulations through annual appropriations bills. Unfortunately, these provisions were dropped when the House and Senate went to conference, and it's unfortunate that it went in that direction, and we hope that we can change that moving forward.

At the FDA, we must ensure that the next commissioner is well educated on the unique nature of the premium cigar industry. This

is why this hearing is important. We are furthering the record that this industry is unlike the other regulated tobacco industries.

We are committed—I know I am, and everyone up here is—to helping this iconic industry and will advocate on behalf of members of the Administration and with our colleagues in Congress, giving premium cigar makers and retailers the clarity and the assurances needed to continue with their craft as a top priority of ours. At a time in which both parties express concern for small businesses and manufacturers and the American working class, this is not an issue that should be controversial.

I hope today's hearing will shed light on how proposed regulations from the FDA will impact this iconic industry, one that is so rooted in our state's history.

On a personal note, I have often told the story of my grandfather, who grew up in Cuba. He was disabled as a young child because he had polio, one of 17 kids in a farming family. And because he couldn't work in the fields, this led him to go to school, where he learned how to read, and I would guess he was one of a few of the 17 who learned how to do so.

And one of the jobs in town for people that knew how to read was a lectore, who would sit in the front of the room as cigars were being rolled in the days before radio and TV and Internet and Siri and all this other stuff, and read them the news, and then he would read novels. If you visit here, you'll see many of the historic cigar rolling rooms where you can envision where the lectore would have sat and would have read. So it's an industry that's near and dear to my heart for that reason as well, and I hope to make a difference for this industry, particularly here in our home state of Florida.

I want to thank, as I said, my two colleagues from the House for being here, for their steadfast support, and I want to recognize Congresswoman Castor to go first. This is her district, and she is the sponsor of this bill in the House.

Thank you so much for being here.

STATEMENT OF HON. KATHY CASTOR, A U.S. REPRESENTATIVE FROM FLORIDA

Representative CASTOR. Good afternoon. Buenas tardes.

Thank you, Chairman Rubio, for holding this hearing, and thank you for your leadership. I want everyone to know that Senator Rubio did have a Tampa Cuban sandwich before this hearing, and he gave the thumbs up on the bread, maybe the best in the state.

Chairman RUBIO. It is.

[Laughter.]

Representative CASTOR. Okay, it's on the record now. It's on the record.

Chairman RUBIO. There are no Miami TV stations here, are there?

[Laughter.]

Representative CASTOR. Well, thanks again for your leadership.

As one of the witnesses here, Mr. Newman, knows, there's not a better place in the country to hold a hearing titled, "Keeping Small Premium Cigar Businesses Rolling" than Tampa, the Cigar City. Premium cigar manufacturing defines Tampa. Over 130 years

ago, Vicente Martinez Ybor moved his factory right here to the heart of my hometown, and his fellow factory owners followed suit. From all over the world, immigrants looking for a better life moved here to work in premium cigar factories. They came from Italy, they came from Spain, from Cuba, indeed from all over the world seeking the American Dream.

And as the industry grew, it became the center of a flourishing multicultural society and the reason that Tampa has become such a proud melting pot. All aspects of life revolved around the business of making premium cigars. Workers would pool their pennies—and I also love the story of the lectore reading to them, providing the news of the day, hearing the great works of fiction to learn English and provide intellectual stimulation. Workers' pennies added up to build the various clubs, the Italian Club, the Cuban Club, Centra Español, Centra Historiano, to name a few, which set the cultural identity of Tampa, provided a place to go to see the doctor or the dentist, or even meet your wife or husband.

Premium cigar manufacturing built Tampa and weaved our sweet, strong social tapestry, and we want to keep it that way.

It was in 2016 when the Food and Drug Administration adopted a rule that applied onerous and burdensome regulations to our city's premium cigar manufacturers. The FDA said it was based on a law to stop the scourge of marketing tobacco products to kids, but I had worked on that law, and the intent was not to include premium cigars. Premium cigars have never been marketed to kids, and I've worked tirelessly in the House of Representatives to help FDA stay focused to protect the public health and to ensure children have adequate, affordable health care, and to ensure that they do not have access to tobacco products. However, the FDA rule went too far, went beyond congressional intent, ignored the distinction between traditional handcrafted premium cigars whose retail model mom-and-pop stores and expensive products ensured that they are not marketed to kids.

This is why I have reintroduced in the House this year my bill, along with my partner, Representative Posey, from the East Coast. This year it's H.R. 1854, the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2019. My bipartisan legislation narrowly focused on premium cigars and reinforces that the FDA does not have the authority to regulate traditional premium cigars, and it will protect mom-and-pop businesses here in Tampa and across the country. The bill currently has 36 bipartisan cosponsors, and I promise to continue my work with my colleagues and community stakeholders to get it across the finish line.

So thank you again, Senator Rubio, Mr. Chairman, and thank you to my good friend and colleague, Congressman Bilirakis. I look forward to working with both of you to ensure that my hometown's premium cigar industry continues to thrive. Thank you very much.

Chairman RUBIO. Thank you, and thank you for hosting this hearing in your district today.

My good friend, Congressman Bilirakis, joins us.

STATEMENT OF HON. GUS BILIRAKIS, A U.S. REPRESENTATIVE FROM FLORIDA

Representative BILIRAKIS. Thank you very much. Thank you, Senator Rubio, Representative Castor. It's great to work with you all in a bipartisan fashion. Let's get this legislation through as soon as possible.

Thank you, Mr. Chairman, for holding this field hearing and for allowing us to participate in this very important discussion. I also wanted to thank the witnesses for their testimony this afternoon.

Small businesses are the backbone of the American economy. They're generating 3.3 million jobs in Florida alone, accounting for over 40 percent of our state's workforce. I have always said that our nation's small businesses are too frequently burdened with increased regulations, and this is a good example of that.

Too often, Federal agencies fail to understand how their regulations and policies harm small businesses across the country, and it is clear to me that the one-size-fits-all approaches to regulate rarely produce the intended results.

My phone is ringing; I'll shut it off. Sorry about that.

Chairman RUBIO. The FDA is calling.

[Laughter.]

Representative BILIRAKIS. As seen by the testimonies this afternoon, the tobacco market is no different. While I'm certainly an advocate for public health, by no means are all products created equal. That's so very important. As we will hear today, the deeming rule's compliance costs have been particularly burdensome for the premium cigar industry, one that is dominated by small businesses, many of which are here in Florida, particularly here in Tampa. Even by FDA's conservative estimates, compliance costs are too much to bear for these small businesses, as Senator Rubio pointed out, all while producing, at best, minimal public health effects.

I'm grateful for the Small Business Administration's Office of Advocacy, which has been a strong voice for small businesses in Florida, promoting regulatory flexibility in the Federal rulemaking process. I firmly believe we can strike a balance to both achieve the goals of FDA to promote public health and safety while at the same time not imposing undue burden on small businesses, such as those here today in the low-volume premium cigar industry.

While the deeming rule was an example of the lack of flexibility, I'm hopeful that we can work in a bipartisan manner, and I know we will, to provide better clarity and less burdensome regulation in the future.

And I yield back, Mr. Chairman. Thank you again for having me here today.

Chairman RUBIO. And thank you for being here.

So, we'll turn to our witnesses. We have a lot of questions for you, I know, so we ask, if possible—I know you've all written statements. Those will all be in the record. If we can keep each one to 4 or 5 minutes so we can get right to the questions, I know the members of Congress that are here may have to leave at some point.

So let's start with Mr. Charles Maresca, the Director of Interagency Affairs for the Office of Advocacy at SBA, the Small Busi-

ness Administration. He leads a team of attorneys that's responsible for reviewing regulations like this one that are issued by other Federal agencies to ensure compliance with the Regulatory Flexibility Act, and obviously to see what impact they have on small business.

Dr. Brad Rodu is the Endowed Chair of the Tobacco Harm Reduction Research Program at the University of Louisville, where he published a book on his research on reducing smoking in Sweden, and he has more than 150 articles and abstracts in peer-reviewed journals attesting to us here of his knowledge of reducing the harmful use of tobacco.

Mr. Jeff Borysiewicz is President and Founder of Corona Cigar Company, which is not only a chain of premium cigar stores and bars, but he also has revived the practice of tobacco growing in Florida, with the Florida Sun-Grown Farm in Claremont. In his spare time, he also co-founded the Cigar Rights of America, and he continues to serve on the board of that group.

And finally Mr. Drew Newman, who is the General Counsel of J.C. Newman Cigar Company, the oldest family-owned cigar company in America, the last of the over 150 active cigar manufacturing facilities that once called Ybor City home. He is also part of that family that founded the company. His great-grandfather founded J.C. Newman in 1895.

So thank you all for being here. We look forward to hearing from all of you.

Let's begin with you, Mr. Maresca.

STATEMENT OF CHARLES MARESCA, DIRECTOR OF INTERAGENCY AFFAIRS, OFFICE OF ADVOCACY, U.S. SMALL BUSINESS ADMINISTRATION

Mr. MARESCA. Chairman Rubio, Representative Castor, Representative Bilirakis, I am honored to be here today on behalf of the U.S. Small Business Administration Office of Advocacy to present testimony to you about the Food and Drug Administration's regulation of premium cigars. As the Director of Interagency Affairs, I manage a team of attorneys who work with Federal Government agencies during the rulemaking process to reduce regulatory burdens on small businesses and to implement the requirements of the Regulatory Flexibility Act. The RFA requires Federal agencies to consider the effects of their proposed rules on small businesses and other small entities, including small governments and small non-profits. Advocacy is an independent office within the SBA that speaks on behalf of the small business community before Federal agencies, Congress, and the White House. The views in my testimony do not necessarily reflect the views of the Administration or the SBA, and this statement has not been circulated to the Office of Management and Budget for clearance.

On April 24th, 2014, FDA issued a proposed rule known as the deeming rule that would deem formerly unregulated or uncovered tobacco products subject to FDA regulation, including premium cigars. The rule became final in May 2016. Advocacy and small businesses in the industry are concerned about the impact this rule would have on the premium cigar industry. Advocacy submitted a comment letter on the deeming rule to FDA on June 11th, 2014.

Because the rule was even then expected to have a significant economic impact on a substantial number of small entities, the FDA included an initial regulatory flexibility analysis, as required by Section 603 of the RFA.

Advocacy's letter stated that FDA's IRFA, Initial Regulatory Flexibility Analysis, was deficient because it neither adequately described the impacts on all the types of newly covered small entities nor explained significant alternatives that might reduce those impacts. Advocacy urged that FDA publish a supplemental IRFA for public comment before proceeding with the deeming rule. FDA did not publish a supplemental IRFA prior to the 2016 final rule. However, on March 26th, 2018, it published an advance Notice of Proposed Rulemaking requesting more information related to the regulation of premium cigars. Specifically, FDA requested comments related to the definition of premium cigars, the use patterns of premium cigars, and the public health considerations associated with premium cigars.

On July 25th, Advocacy submitted a comment letter on the AMPRM reiterating our 2014 comment letter urging FDA to include a more robust economic analysis of the rule's impact on small business and to include a description of significant alternatives that would minimize that impact when it publishes an IRFA for its proposed rule on the regulation of premium cigars.

Since June 2017, Advocacy has traveled to 24 states to host regional roundtables and to hear from small businesses about the regulatory issues with which they are most concerned. We hosted three of those roundtables in Florida, including one here in Tampa, and we heard compelling stories from small business owners in the premium cigar industry at many of those roundtables.

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

According to FDA's own estimates, the deeming rule's compliance costs will have significant impacts on small businesses. Specifically, FDA states that some low-volume cigar manufacturers may end their domestic operations entirely. Although many small businesses have argued that the costs will be much higher than FDA's estimates, the costs foreseen by the agency's own numbers will prove to be too much for most small businesses to pay to continue to manufacture premium cigars.

The premium cigar industry has argued that one report under the rule could cost up to $250,000. For manufacturers who cannot afford the deeming rule's compliance costs and are forced to shutter their factories, there will be thousands of employees who will no longer be employed. Cigar Rights of America estimates that there are approximately 35,000 jobs associated with the premium cigar industry, which includes manufacturing and retail employees.

While FDA has stated the objectives of the deeming rule under the authorizing statute, it is still required by the RFA to require significant alternatives to the rule that would minimize the impact

on small businesses, and we again reiterate our 2014 recommendations in that regard.

Thank you for this opportunity to testify on behalf of small businesses, and I would be happy to answer any questions you might have.

[The prepared statement of Mr. Maresca follows:]

U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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Testimony of

Charles Maresca
Director of Interagency Affairs
Office of Advocacy
U.S. Small Business Administration

United States Senate
Committee on Small Business and Entrepreneurship

Date:	April 5, 2019
Time:	1:00 P.M.
Location:	Performing Arts Building Auditorium Hillsborough Community College, Ybor City Campus 2112 N. 15th Street Tampa, FL
Topic:	Keeping Small Premium Cigar Businesses Rolling

Chairman Rubio, Ranking Member Cardin, Members of the Committee, I am honored to be here today on behalf of the U.S. Small Business Administration (SBA) Office of Advocacy (Advocacy) to present testimony to you about the Food and Drug Administration's (FDA) regulation of premium cigars.

As the Director of Interagency Affairs, I manage a team of attorneys who work with federal government agencies during the rulemaking process to reduce regulatory burdens on small businesses and to implement the requirements of the Regulatory Flexibility Act (RFA). The RFA requires federal agencies to consider the effects of their proposed rules on small businesses and other small entities, including small governments and small nonprofits. Advocacy is an independent office within the SBA that speaks on behalf of the small business community before federal agencies, Congress, and the White House. The views in my testimony do not necessarily reflect the views of the Administration or the SBA, and this statement has not been circulated to the Office of Management and Budget for clearance.

Advocacy's Involvement in the Regulation of Premium Cigars

The Family Smoking Prevention and Tobacco Control Act was signed into law in 2009; it amended the Federal Food, Drug, and Cosmetic Act and gives FDA the power to regulate "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" and "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter."[1] On April 24, 2014, FDA issued a proposed rule (the "Deeming Rule") that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars.[2] The proposed rule subjected newly covered products to regulatory requirements applicable to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. These requirements included general controls, health warnings, and sales and marketing restrictions. Additionally, the proposed rule required a previously uncovered product to be subject to FDA premarket authorization before being marketed in the United States if the product was "new." A "new" tobacco product was one that was not marketed as of February 15, 2007. Manufacturers of such products must submit either a Premarket Tobacco Application or

[1] 21 U.S.C. § 387a(b) (2009).
[2] Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142 (proposed Apr. 25, 2014), (to be codified at 21 C.F.R. pts. 1100,1140, & 1143).

a Substantial Equivalence (SE) Report to or request a Minor Modification Exemption from FDA.

On June 11, 2014, Advocacy submitted a comment letter on the Deeming Rule to FDA, addressing the agency's Initial Regulatory Flexibility Analysis (IRFA) under the RFA.[3] An IRFA is required to contain: (1) a description of the reasons why action by the agency is being considered; (2) a succinct statement of the objectives of, and legal basis for, the proposed rule; (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply; (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; (5) an identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and (6) a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.[4] In its letter, Advocacy stated that FDA's IRFA was deficient because it neither adequately: (1) described the impacts on all of the types of newly covered small entities, nor (2) explained significant alternatives that might reduce those impacts. Advocacy suggested that FDA publish a Supplemental IRFA for public comment before proceeding with the Deeming Rule.

FDA did not publish a Supplemental IRFA, and on May 10, 2016, the Deeming Rule became final. Notably, one alternative FDA had considered in the proposed rule was the possible exemption of premium cigars from the rule. However, FDA found "no appropriate public health justification to exclude premium cigars;" therefore, premium cigars were not exempted from the final Deeming Rule.[5]

On July 28, 2017, FDA announced a new comprehensive plan for regulating tobacco and nicotine.[6] To that end, on March 26, 2018, it published an advance notice of proposed rulemaking entitled *Regulation of Premium Cigars*, requesting more

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[3] The comment letter is attached as Appendix 1.
[4] 5 U.S.C. § 603 (2019).
[5] Deeming Tobacco Products to Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Control Act; Restriction on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28,974, 29,020 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, & 1143).
[6] Food & Drug Admin., *News Release: FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

information related to the regulation of premium cigars.[7] Specifically, FDA requested comments related to the definition of premium cigars, the use patterns of premium cigars, and the public health considerations associated with premium cigars.[8]

On July 25, 2018, Advocacy submitted a comment letter on the advanced notice of proposed rulemaking to FDA.[9] As we stated in our 2014 comment letter on the Deeming Rule, Advocacy again urged FDA to include a more robust economic analysis of the rule's impact on small businesses and a description of significant alternatives that would minimize that impact when it publishes an IRFA for its proposed rule on the regulation of premium cigars. Advocacy also resubmitted its 2014 Deeming Rule comment letter to FDA. To date, FDA has not published a notice of proposed rulemaking for the regulation of premium cigars. Advocacy's request is consistent with the Congressional intent underlying the RFA, that when adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively as possible without imposing unnecessary burdens on the public.

Between June 2017 and September 2018, Advocacy hosted 33 regional roundtables in 22 states to hear from small businesses about the regulatory issues with which they are most concerned. We hosted three such roundtables in Florida, including one here in Tampa. Advocacy heard compelling stories from small business owners in the premium cigar industry at many of those roundtables. In December 2018 Advocacy published its progress report about the issues discussed at those regional roundtables. I am also pleased to announce that Advocacy's RFA Annual Report for fiscal year 2018 was delivered to Congress this week.

The Deeming Rule's Effect on Premium Cigars

Attached to this testimony is a thumbnail sketch of the premium cigar industry.[10] Advocacy believes that small businesses dominate the premium cigar industry. There are at least 50 manufacturers of premium cigars across 19 states or more, all small businesses.[11] Indeed, over 20 of those manufacturers are in Florida alone. Additionally,

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[7] Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (proposed Mar. 26, 2018), (to be codified at 21 C.F.R. pts. 1100, 1140, & 1143).
[8] *Id.* at 12,903.
[9] The comment letter is attached as Appendix 2.
[10] *See* Appendix 3.
[11] In its Final Regulatory Flexibility Analysis (FRFA) for the Deeming Rule, FDA states that according to the Alcohol and Tobacco Tax and Trade Bureau (TTB) there were 113 domestic cigar manufacturers in 2013. The TTB does not differentiate between premium and non-premium cigar manufacturers for tax purposes. *See also* Appendix 3.

there are over 3,000 retailers of premium cigars located in all 50 states, some of which also roll their own cigars and are considered manufacturers under FDA's Deeming Rule.

According to FDA's own estimates, the Deeming Rule's compliance costs will have significant impacts on small businesses. Specifically, FDA states that some "low-volume cigar" manufacturers may end their domestic operations entirely.[12] Premium cigar manufacturers are the very definition of "low-volume" cigar manufacturers. Their cigars are handmade and labor intensive, manufactured by the hundreds per day as opposed to the thousands an hour for mass-marketed, machine-made cigars.

For a small business cigar manufacturer, FDA estimates compliance costs to be $278,000 to $397,000 in the first year, $292,000 to $411,000 in the second year, and $235,000 to $257,000 in the third year.[13] Although many small businesses have argued that the costs will be much higher than FDA's estimates, the agency's own numbers will prove to be too much for most small businesses to pay to continue to manufacture premium cigars. Included in those costs would be applying for premarket approval or completing an SE Report. An SE Report for cigars includes a detailed chemical analysis of: (1) the cigar itself, (2) the cigar band paper and ink, (3) the wood of the cigar box, and (4) the cellophane wrapper in which the cigars are wrapped. The premium cigar industry has argued that one SE Report could cost up to $250,000.[14]

For manufacturers who cannot afford the Deeming Rule's compliance costs and are forced to shutter their factories, there will be thousands of employees who will no longer be employed. Cigar Rights of America estimates that there are approximately 35,000 jobs associated with the premium cigar industry, which includes manufacturing employees, retail employees, and other employees throughout the industry's supply chain.[15]

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[12] Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements FRFA, Docket No. FDA-2014-N-0189, at 70, *available at* https://www.regulations.gov/document?D=FDA-2014-N-0189-83196.

[13] *Id.* at 132.

[14] Comment Letter from Cigar Association of America, Inc. to FDA Division of Dockets Management RE: Docket No. FDA-2017-N-5095 (Feb. 5, 2018), at 17, *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-5095-0032&attachmentNumber=1&contentType=pdf.

[15] Comment Letter from Norton Rose Fulbright, US LLP to The Honorable Scott Gottlieb RE: Comment of the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America on Docket No. FDA-2017-N-6107, Regulation of Premium Cigars (July 25, 2018), at 74, *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-6107-8796&attachmentNumber=1&contentType=pdf.

Conclusion

While FDA has stated the objectives of the deeming rule under the authorizing statute, it is still required by the RFA to consider significant alternatives to the rule that would minimize the impact on small businesses. Advocacy and small businesses are extremely concerned about the Deeming Rule's effects on small premium cigar businesses. Indeed, Advocacy made its concerns known to FDA in 2014, and those concerns have not changed. FDA must conduct a more robust economic analysis on the rule's impacts on small businesses, specific to the affected premium cigar industry, and consider significant alternatives to those impacts to accomplish the agency's stated objective while keeping small premium cigar manufactures and retailers in business. I would be happy to answer any questions you may have.

U.S. Small Business Administration

409 3rd Street SW / MC 3110 / Washington, DC 20416 /
Ph 202-205-6533 / advocacy.sba.gov

Created by Congress in 1976, the Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. The Chief Counsel for Advocacy, who is appointed by the President and confirmed by the U.S. Senate, directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Issues are identified through economic research, policy analyses, and small business outreach. The Chief Counsel's efforts are supported by offices in Washington, D.C., and by Regional Advocates. For more information about the Office of Advocacy, visit http://www.sba.gov/advocacy, or call (202) 205-6533.

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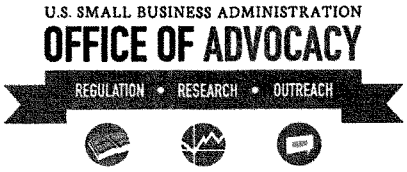

Appendix 1

SBA Office of Advocacy June 11, 2014, Comment Letter RE: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, Docket No. FDA-2014-N-0189

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Advocacy: the voice of small business in governme

June 11, 2014

VIA ELECTRONIC SUBMISSION

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993
http://www.regulations.gov

Re: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, Docket No. FDA-2014-N-0189

Dear Commissioner Hamburg:

The Office of Advocacy (Advocacy) offers the following comment to the Food and Drug Administration (FDA) in response to the above-referenced proposed rule issued on April 24, 2014.[1] The FDA issued the proposed rule to implement provisions of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act)[2]. Since the passage of the Tobacco Control Act, small businesses that manufacture or market tobacco products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA promulgated this proposal, small business owners continued to contact and meet with Advocacy to convey feedback about the proposed rule. Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA)[3]. Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

[1] 79 Fed. Reg. 23,142 (April 25, 2014). Proposed rule available at: https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.
[2] 21 U.S. Code § 387a.
[3] 5 U.S.C. § 601 et seq.

Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

The RFA requires agencies to give every appropriate consideration to comments provided by Advocacy. The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[5]

Background

The Tobacco Control Act authorizes the FDA to regulate the manufacture, distribution, and marketing of tobacco products to "protect public health." The Tobacco Control Act provides that other tobacco-related products can be subject to FDA regulation if the agency deems them to be regulated products under a rulemaking process referred to as the "deeming regulation."

On April 24, 2014, the FDA Center for Tobacco Products issued a proposed rule that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars, e-cigarettes, and hookah tobacco. In the release, the FDA proposes and requests comment on an option where it would not deem (i.e., the agency would exempt) premium cigars. The FDA is considering this option because "it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation and frequency of use by youth and young adults."[6]

The deeming regulations would subject newly covered products to regulatory requirements currently only applicable to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. These requirements include general controls, health warnings, and sales and marketing restrictions. Additionally, under the proposal, a previously uncovered product would be subject to FDA premarket authorization before it may be marketed in the United States if the product is "new." A tobacco product is considered "new" if it was not being marketed as of February 15, 2007 (the "Grandfather Date") or if any modification has been made to the product that was on the market before the Grandfather Date. If the FDA treats a product as "new," the product manufacturer must submit to the FDA either a Premarket Tobacco Application, a Substantial Equivalence (SE) Report, or request a Minor Modification Exemption. For purposes of an SE report, a business must cite a predicate product that was commercially marketed as of the

[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).
[5] 5 U.S.C. § 601 et seq.
[6] See proposed rule at page 8.

Grandfather Date, and contain detailed information about the cited predicate product, including complete specifications, ingredient and component information, manufacturing information, and product testing data.

In the proposal, the FDA observes that "approximately 90 percent of domestic entities affected by this rule are estimated to be small." The FDA estimates that upfront costs for small businesses will measure approximately $390,000 - $759,000 and that annual compliance costs for small businesses will measure approximately $450,000 - $541,000.[7] The FDA notes that the annual costs of the proposed rule are expected to be greater than 10 percent of sales for small manufacturers / producers. However, the FDA's Preliminary Regulatory Impact Analysis (PRIA) and IRFA[8] suggest that there is uncertainty around these cost estimates. In several portions of its analysis, the FDA concedes that it has not accurately quantified all of the costs and burdens associated with extending its authority to regulate previously uncovered products.[9]

Since the passage of the Tobacco Control Act, small businesses that manufacture or market previously uncovered products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA issued the proposal, small business owners have continued to contact Advocacy to convey concerns related specifically to the proposed rule. Advocacy has heard from small businesses that market and sell tobacco products as well as previously uncovered products, small businesses in the "little cigar" industry, small businesses in the "premium cigar" industry, small businesses in the e-cigarette industry, and small businesses in the hookah industry.

The Proposed Rule's IRFA is Deficient

Because it does not adequately describe the impacts on all types of newly covered small entities and because it does not adequately explain significant alternatives that might reduce those impacts, Advocacy believes that the IRFA contained in the proposed rule is deficient, and for this reason, the FDA should republish a Supplemental IRFA for additional public comment before proceeding with this rulemaking. Under the RFA, an IRFA must contain: (1) a description of the reasons why the regulatory action is being taken; (2) the objectives and legal basis for the proposed regulation; (3) a description and estimated number of regulated small entities; (4) a description and estimate of compliance requirements, including any differential for different categories of small entities; (5) identification of duplication, overlap, and conflict with other rules and regulations; and (6) a description of significant alternatives to the rule.[10] Advocacy is concerned that because the proposed rule's IRFA is deficient, the public has not been adequately informed about the possible impact of the proposal on small entities and whether there are less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives.

Given the scope of the proposal and the number of small entities that would be impacted by it, the IRFA should include more data and analysis to provide the public with sufficient information on the economic impact of the proposed rule. However, the IRFA contained in the proposed rule

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[7] See proposed rule at page 191.
[8] PRIA and IRFA available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf.
[9] See, e.g., PRIA at pages 7, 12, 25, and 41.
[10] 5 USC § 603.

does not adequately describe and estimate the costs the proposal would impose on small entities by both omitting a substantive discussion of costs that accrue to products with many small entities and understating compliance costs. As described above, the FDA does not quantify many of the costs and burdens associated with the proposed rule in the IRFA even for product categories where the agency estimates there are a sizeable number of small manufacturers. Instead, the FDA presents data and analysis only for cigar manufacturers and uses a limited dataset that does not measure burgeoning marketplaces such as online sales.

Many small businesses have expressed concern to Advocacy regarding costs related to premarket submissions that the proposed rule would require. These small businesses have explained to Advocacy that the cost estimates in the IRFA may be understated because the FDA does not account for differences in the way that small business will comply with the proposed rule. As an example, the FDA does not recognize that the proposal may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses.

Additionally, many small businesses have told Advocacy that they will have trouble utilizing the less burdensome SE premarket submission process. Because businesses in industries for newly covered products would not be able to obtain marketing orders as many of these industries, such as e-cigarettes, were not in existence as of the Grandfather Date, or they rely on proprietary technologies. Small businesses have even confided to Advocacy that the costs associated with the proposal's premarket submission requirements could force many of them to exit the market and cease operating.

Taking into account the potentially extensive costs of the proposal, the IRFA does not fully consider significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. All of the alternatives currently considered in the IRFA would only make marginal changes to the overall compliance costs to small entities, such as exempting products from labeling changes. Therefore, Advocacy encourages the FDA to further consider alternatives that may be able to more greatly decrease the regulatory burden on small business while still allowing the FDA to meet its regulatory goals.

The RFA provides guidance on this issue and it instructs agencies that when faced with economic impacts as significant as those estimated by the FDA, agencies should consider alternatives such as: (1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) use of performance rather than design standards; and (4) exemption for certain or all small entities from coverage of the rule, in whole or in part.[11] Advocacy believes that all of these categories of alternatives would be relevant and useful to consider as a part of this rulemaking.

Notably, the proposed rule considers some of these alternatives for one specific product category: premium cigars. In the proposal, the FDA provides detailed data showing why the agency is considering this alternative and the cost savings that exempting premium cigars would yield. While Advocacy appreciates this example of an alternative that could meet regulatory goals while significantly reducing regulatory burdens, the FDA however does not provide an analysis related

[11] See 5 U.S.C. § 603(c).

to this alternative in the IRFA for premium cigars or any other product. Advocacy is unsure of why the FDA would not consider this significant alternative in the proposal's IRFA. Further, Advocacy is concerned that the FDA did not discuss and consider other alternatives in the IRFA that would yield similar significant cost savings as exempting premium cigars would, and that the agency did not perform a similar level of analysis on the alternatives listed in the IRFA as the agency did do elsewhere in the rule related to premium cigars. Advocacy recommends that FDA extend the analysis done on premium cigars to more product types so that the FDA can ensure that it is proposing the most effective and efficient regulation possible.

Recommendations

Advocacy recommends that the FDA revise the IRFA to provide a more accurate description of the costs of the proposed rule by including a quantitative analysis of all product categories that are manufactured or marketed by small businesses. Specifically, although the FDA notes in the proposed rule that it expects the proposal to directly impact small businesses that market or manufacture cigars, pipe tobacco, hookah, and e-cigarettes, the FDA does not provide a detailed analysis of the potential impact on many of the small entities for newly covered products. As described above, the FDA provides a detailed analysis for only one alternative – not deeming premium cigars – that would yield significant cost savings for certain small businesses. Advocacy encourages the FDA to apply this analysis elsewhere in the IRFA so that not deeming other product categories can be considered and comprehensively discussed. The FDA should develop an alternative to consider regarding not deeming other "premium" products that are similarly marketed, designed, and used as premium cigars. The FDA should also provide additional data and analysis to illustrate why the benefits of deeming some of these products outweigh the substantial costs.

Advocacy also believes that even if an alternative is discussed elsewhere in the proposed rule, for purposes of the RFA analysis, it should be discussed in the IRFA portion of the proposal to allow for more substantive public comment and improved transparency around the FDA's analysis. Moreover, to improve the quality of comments received by the public and to ensure a comprehensive review under the RFA where FDA chooses to reject an alternative, the FDA should provide a policy or economic justification as to why it did not adopt each particular alternative considered.

Advocacy also recommends that the FDA should take into consideration small business stakeholders' suggested alternatives to minimize the proposed rule's potential impact. Small business representatives in contact with Advocacy observe that the FDA could still achieve its stated purposes for the premarket submission process in the deeming proposal through the use and enforcement of statutes and regulations already in effect. As an example, small business representatives note that under 21 U.S.C. § 387d(a)(1) and § 387d (c), manufacturers and importers of regulated tobacco products are required to submit (and update) specific information about the ingredients in each marketed product. Similarly, 21 U.S.C. § 387e mandates the registration of all domestic tobacco product manufacturing establishments and product listings for all regulated tobacco products manufactured at such establishments. Advocacy encourages the FDA to review and discuss statutes and regulations currently in effect as suggested by small

business stakeholders that may already achieve the purposes of the premarket submission process in the deeming proposal.

Finally, Advocacy would like the FDA to provide at least a 90-day comment period for the proposed rule given the large economic impact that it is estimated it will have on small business. Small business will need sufficient time to analyze the potential impact of this proposed rule.

Conclusion

Advocacy is concerned that the FDA's proposed rule and IRFA lack essential information needed to properly inform the agency's decision making. Specifically, the IRFA does not adequately describe the costs of the proposed rule on small entities, and the IRFA does not set forth, consider, and discuss significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

By republishing a Supplemental IRFA, small businesses will have more adequate data to assess the potential impact of the proposed rule. The FDA will further gain valuable insight into the effects of the proposed rule on small business and be more transparent in explaining and justifying the choices that it made in the proposal. Advocacy also believes that the FDA should take into consideration small business representatives' suggested alternatives that may minimize the proposed rule's potential impact.

Advocacy is committed to helping the FDA comply with the RFA in the development of the proposed rule. Therefore, Advocacy stands ready to assist the FDA in the completion of a Supplemental IRFA. Advocacy looks forward to working with the FDA. If you have any questions or require additional information please contact me or Assistant Chief Counsel Dillon Taylor at (202) 401-9787 or by email at Dillon.Taylor@sba.gov.

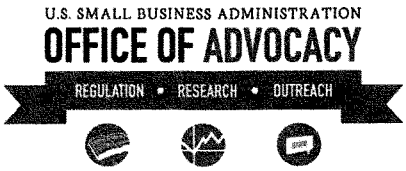
Sincerely,

Winslow Sargeant

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Dillon Taylor
Assistant Chief Counsel Advocacy

Copy to: The Honorable Howard Shelanski, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget



Appendix 2

SBA Office of Advocacy July 25, 2018, Comment Letter RE: Regulation of Premium Cigars, Advanced Notice of Proposed Rulemaking, 83 Fed. Reg. 12901 (March 26, 2018) (Doc. No. FDA-2017-N-6107)

SBA U.S. Small Business Administration

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U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

July 25, 2018

VIA ELECTRONIC SUBMISSION

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

Re: Regulation of Premium Cigars, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12901 (March 26, 2018) (Doc. No. FDA-2017-N-6107).

Dear Commissioner Gottlieb:

On March 26, 2018, the Food and Drug Administration (FDA) published an advance notice of proposed rulemaking entitled: *Regulation of Premium Cigars.*[1] The U.S. Small Business Administration's Office of Advocacy (Advocacy) appreciates the FDA's solicitation for more information related to the regulation of premium cigars and welcomes the opportunity to provide input on behalf of small business stakeholders. Advocacy recommends the agency consider and explain all significant alternatives in order to minimize the significant economic impact of any proposal on small entities.

The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant

[1] *See* Food and Drug Admin.; *Regulation of Premium Cigars*, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 12901 (March 26, 2018).
[2] *See* 5 U.S.C. § 601 et seq.
[3] *See* Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).

economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

Background

On June 22, 2009 the Tobacco Control Act was enacted and provided the FDA with authority to regulate the manufacture, distribution, and marketing of tobacco products to "protect the public health."[4] The Tobacco Control Act further provides that other tobacco-related products can be subject to regulation if the FDA deems them to be regulated products under a rulemaking process referred to as the "deeming regulation."

On April 24, 2014 the FDA issued a proposed deeming regulation that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars.[5] On, June 11, 2014, Advocacy submitted comments on the proposed rule, citing concerns that the proposed rule's Initial Regulatory Flexibility Act Analysis (IRFA) did not adequately consider or explain significant alternatives which could accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities.[6] A copy of the letter is attached. The deeming rule became final on May 10, 2016.[7] While one of the proposed rule's options contained an exemption for premium cigars, the final rule ultimately included premium cigars within the scope of the final rule.[8] On July 28, 2017, the FDA announced a new comprehensive plan for regulating tobacco and nicotine.[9] Pursuant to these efforts, on March 26, 2018, the FDA published an advance notice of proposed rulemaking seeking additional information related to the regulation of premium cigars.

Small Businesses are Concerned about the Impacts of Premium Cigar Regulation

In its June 11, 2014 letter, Advocacy voiced concerns the proposed deeming rule's IRFA was deficient, and therefore the public had not been adequately informed about the possible impact of the proposal on small entities and whether there were less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives. Many of the small business concerns cited in Advocacy's previous letter still remain – including concerns related to the cost of premarket submissions and the potentially extensive costs of complying with any regulatory proposal.

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[4] *See* Tobacco Control Act of 2009 (Pub. L. 111-31) amending FD&C Act, § 901, 21 U.S.C. 387a.
[5] *See* 79 Fed. Reg. 23142 (April 25, 2014).
[6] *See* SBA Office of Advocacy, *Letter re: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, Docket No. FDA-2014-N-0189* (June 11, 2014), https://www.sba.gov/advocacy/61114-deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act-amended-family.
[7] *See* 81 Fed. Reg. 28974 (May 10, 2016).
[8] *See id.* at 29020.
[9] *See* Food and Drug Admin., *News Release: FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

Advocacy's Recommendations

Advocacy expects that any regulation of the premium cigar industry under the deeming rule would include a more robust economic analysis of the rule's impact on small businesses, and a description of significant alternatives that would minimize that impact. As we pointed out in our 2014 letter, the Regulatory Flexibility Act itself provides guidance on alternatives that the FDA should consider as a minimum: (1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) use of performance rather than design standards; and (4) exemption for certain or all small entities from coverage of the rule, in whole or in part.[10]

Advocacy is encouraged that FDA has taken this step to acquire information that it would need to evaluate these alternatives and the significant alternatives that have been put forward by small businesses in the industry. Advocacy expects that in any proposed rulemaking FDA will include a full analysis of all significant alternatives and a fully explained rationale for its preferred alternative.

Conclusion

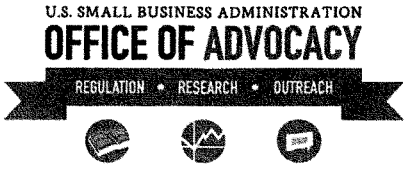
In response to the agency's notice, Advocacy submits the above comments and resubmits its previous comments to assist the agency as it prepares its proposed rulemaking and any related RFA analysis. Advocacy recommends that the agency consider and explain all significant alternatives in order to minimize the significant economic impact of any proposal on small entities. If you have any questions or require additional information please contact me or the Director of the Office of Interagency Affairs, Charles Maresca, at (202) 205-6978 or by email at charles.maresca@sba.gov.

Sincerely,

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Charles A. Maresca
Director of the Office of Interagency Affairs
Office of Advocacy
U.S. Small Business Administration

[10] *See* 5 U.S.C. § 603(c).



Appendix 3

Summary of the Premium Cigar Industry Prepared by SBA Office of Advocacy

SBA U.S. Small Business Administration

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Summary of the Premium Cigar Industry
Prepared by SBA Office of Advocacy

Industry

The premium cigar industry includes retailers, manufacturers, distributors, importers, and growers. Direct effects of the rule are mostly on manufacturers and importers. However, many retailers are also manufacturers or importers.

Premium cigars represent a very small part of the tobacco industry.

- Large cigars are about 5% of all cigars and cigarettes produced in or imported to the U.S. by volume, and premium cigars are a fraction of large cigars.[1]
- Premium cigars make up less than 3% of the cigar market.[2]

The premium cigar industry is predominately made up of small businesses.

- According to Food and Drug Administration, most cigar manufacturers are small, operating from a single establishment.[3] The SBA size standard for tobacco manufacturing (NAICS 312230), an industry classification that includes all manufacturers of tobacco products such as cigarettes, cigars, and pipe tobacco, is 1,500 employees.[4] In the tobacco manufacturing industry, 93% of businesses are small. According to Census Bureau economic data, there are only 9 firms within the tobacco manufacturing industry with more than 500 employees.[5]
- The SBA size standard for tobacco stores (NAICS 453991) is $7.5 million in average annual revenue. There are over 9,000 tobacco stores in the U.S., and 97% of them are small businesses.[6] According to industry, about a third of tobacco stores sell premium cigars, and many stores make their own premium cigars as well.[7]

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[1] U.S. Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau, Statistical Report-Tobacco Products (Mar. 12, 2018), https://ttb.gov/statistics/2018/201812tobacco.pdf.
[2] *Id.* (premium cigar share estimated using the highest taxed subgroup of cigars). The TTB does not differentiate between premium and non-premium cigar manufacturers for tax purposes.
[3] Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis (May 2016), https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf.
[4] U.S. Small Business Administration, Small Business Size Standards Matched to North American Industry Classification System Codes (Oct. 1, 2017), https://www.sba.gov/sites/default/files/2018-07/NAICS%202017%20Table%20of%20Size%20Standards.pdf.
[5] U.S. Census Bureau, 2016 SUSB Annual Data Tables by Establishment Industry (Dec. 4, 2018), https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html.
[6] U.S. Census Bureau, 2012 SUSB Annual Data Tables by Establishment Industry (Oct. 3, 2016), https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.
[7] Comments of J.C. Newman Cigar Company, Regulation of Premium Cigars (Jul. 25, 2018), https://www.regulations.gov/document?D=FDA-2017-N-6107-8608.

Economic Impacts

Estimated compliance costs of the deeming rule could eclipse the total sales for many premium cigar manufacturers. Retailers that sell premium cigars will also be affected.

- Based on Dun & Bradstreet data, a report commissioned by Cigar Rights of America estimated the median annual revenue for cigar manufacturers to be $252,580.[8] According to Census data, 28 tobacco manufacturers make less than $1 million in annual revenue, and small tobacco stores average $779,816 in annual revenue.[9]
- Total first-year cost of the rule for a typical small manufacturer or importer according to the FDA is: $277,750-$397,350.[10] Compliance costs for affected small tobacco store retailers that sell cigars, such as lost sales, were not quantified by FDA. However, to the extent that retailers also make premium cigars, it is likely that the new requirements will force them to cease manufacturing activity.

Affected Small Entities-Manufacturers

Economic data from the Census Bureau covers the tobacco industry broadly and does not break out the cigar or premium cigar industries specifically. In the absence of specific Census data, Advocacy identified premium cigar manufacturers in the U.S. using media coverage of the industry and information provided by trade associations.[11] We found that:[12]

- There are at least 56 cigar manufacturers in the U.S.
- These manufacturers are located in 19 states, with over 20 located in Florida.
- Of these manufacturers, 49 are also retailers.

Nearly all the manufacturers we identified were small-scale operations with a single location.

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[8] *The Public Health, Financial and Employment Impacts of Excluding Handmade Cigars from Coverage by FDA's Final Rule*, Magnum Economics (October 2018), https://cigar-coop.com/wpcontent/uploads/2018/12/Magnum_Study.pdf.

[9] *See* footnote 6.

[10] *See* footnote 3.

[11] Gregory Mottola, *50 Factories in the U.S. That Still Make Cigars*, Cigar Aficionado (Jan. 31, 2019), https://www.cigaraficionado.com/article/50-factories-in-the-u-s-that-still-make-cigars.

[12] We removed one business from the *Cigar Aficionado* list that had exited manufacturing, one business that appeared to have closed, and one retailer that we could not confirm was also a manufacturer. One firm had three establishments listed, and we counted this as a single firm. We also added 11 additional manufacturers not included in the original list. Our list represents a lower bound on the number of cigar manufacturers in the U.S., as there are likely to be a number of manufacturers we did not locate.

Chairman RUBIO. Thank you very much.
Dr. Rodu.

STATEMENT OF DR. BRAD RODU, ENDOWED CHAIR, TOBACCO HARM REDUCTION RESEARCH, UNIVERSITY OF LOUISVILLE

Dr. RODU. Chairman Rubio, members of Congress, thank you very much for the invitation to participate.

As an oral pathologist at a major cancer center 25 years ago, I discovered that Americans, including doctors, are grossly misinformed about the health risks of cigarettes versus the vastly lower risks of dip and chew products; that is, smokeless tobacco. This launched my tobacco research program that has produced the publications that Chairman Rubio referred to in the peer-reviewed medical literature.

My research established that smokeless tobacco use is 98 percent less hazardous than smoking, and that extends to the risk for mouth cancer. This was confirmed by a large recent study from Federal and Federally-funded investigators. They found that men who dipped or chewed tobacco had no excess risk for mouth cancer—zero.

Differences in health effects are also well documented for combustible products. First, some basic principles. When you burn tobacco, you release nicotine and about 7,000 other chemicals. Twenty to 30 years of 10 deep puffs on 20 to 30 cigarettes a day builds high risks for cancers, circulatory diseases, and emphysema, leading to a high death toll.

Cigars also involve burning tobacco, but patterns of use are completely different. The FDA knows that the cigar category encompasses a wide spectrum of products. One is premium cigars. The rest of the category consists of machine-made, mass-produced cigarillos, little cigars and filtered cigars, and I will refer to all of those as little cigars.

In 2014, FDA staff estimated that less than 1 percent of Americans smoked premium cigars. Most light up infrequently. Consumers of little cigars smoke a lot more often, and they also tend to smoke cigarettes.

Premium cigar smokers fit another FDA label, primary; that is, they never smoked cigarettes, as opposed to former smokers who have switched over to cigars and dual users of both products, again mostly little cigars. This is important because adding cigarettes adds risk.

In my submitted testimony I present detailed information from a published FDA analysis of 22 epidemiologic studies of the causes of death among cigar smokers, most of whom, of course, are men. The FDA study listed many diseases associated with cigarette smoking. The biggest killers are cancers, heart disease, stroke and emphysema. Consumption of one or two cigars per day was not associated with significantly increased deaths from any of these diseases in the FDA study.

To be clear, puffing or inhaling the smoke of burning tobacco is not a healthy activity. But the FDA researchers misstated the facts when they concluded that, quote, "Cigar smoking carries many of the same risks as cigarette smoking," end quote.

All tobacco consumers deserve truthful information and guidance. The sweeping FDA indictment ignores scientific evidence and misleads cigar smokers. The following facts are indisputable.

In the U.S., the prevalence of cigar use, especially premium cigars, is very low.

Number two, premium products are used infrequently and in small numbers.

And number three, they are puffed rather than inhaled.

Low prevalence, infrequent use, and reduced exposure translates into minimal harm at the population level.

Conflation of cigarette smoking with dip and chew, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally dangerous. When Congress gave the FDA regulation of tobacco products 10 years ago, it did not direct the agency to treat all tobacco products as equally hazardous. Unfortunately, the FDA's regulatory actions have done just that.

The FDA's current posture wastes government resources, undermines public health, and does nothing to address the half-million deaths caused by cigarette smoking.

Thank you.

[The prepared statement of Dr. Rodu follows:]

U.S. SENATE
COMMITTEE ON SMALL BUSINESS & ENTREPRENEURSHIP

Friday April 5, 2019

1:00 p.m.

Performing Arts Building
Ybor City Campus, Hillsborough Community College
Tampa, FL

Hearing: Keeping Small Premium Cigar Businesses Rolling

Prepared Testimony By:
Brad Rodu, DDS
Professor, Department of Medicine
Endowed Chair, Tobacco Harm Reduction Research
School of Medicine
University of Louisville

Brad Rodu
Prepared Testimony
April 5, 2019

Summary

- Cigarette smoking is associated with high risks for cancers, circulatory diseases and emphysema. Every year, nearly 500,000 adults die from smoking-related diseases. For the past 50 years, the American cancer "epidemic" has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.

- Compared with cigarette smoking, prevalence of cigar use is much lower; in 2014 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made products.

- Compared with cigarettes, other tobacco products are associated with considerably lower health risks. Smoke-free tobacco products are vastly less hazardous than combustible products. Among combustible products, epidemiologic studies document that cigar smoking is much less hazardous than cigarette smoking.

- A recent FDA study found that consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, smoking-related cancers, coronary heart disease, stroke, or emphysema.

- With low prevalence and minimal to no adverse health effects, regulation of cigars will have negligible impact on public health.

- FDA's unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. This posture wastes government resources, undermines public health and does nothing to address the deaths caused by cigarette smoking.

Brad Rodu
Prepared Testimony
April 5, 2019

I was trained as an oral and maxillofacial pathologist 40 years ago. By the early 1990's, I had been on the staff of the Comprehensive Cancer Center at the University of Alabama at Birmingham for 10 years. At this large academic medical center, I watched countless patients succumb to cancers and other diseases caused by cigarette smoking. I had been educated to believe that all tobacco products were equally hazardous. However, my experience providing pathologic diagnoses for hundreds of mouth cancers did not sync with what I had been taught. The vast majority of the patients I diagnosed were cigarette smokers and/or heavy drinkers. Virtually none of them had used moist snuff or chewing tobacco, despite the fact that these products were commonly used in the deep South.

I resolved the discrepancy by conducting research, resulting in the publication of 70 articles in peer-reviewed medical journals (1). I documented that, compared with cigarette smoking, smokeless tobacco use is 98% less hazardous, even for mouth cancer. In fact, a large recent study from federal and federally-funded investigators found that men who dipped or chewed tobacco had no excess risk for that disease (2). In addition, an American Cancer Society report on the top causes of 660,000 cases of cancer in the U.S. (3) ranked cigarette smoking #1, while smokeless tobacco did not even make the list.

The principal takeaway here is that all tobacco products do not have the same health risks. This also applies to combustible products like cigars, according to research from FDA officials (4).

Cigar Smokers

The cigar category encompasses a diverse spectrum of products. On one end are premium cigars that are hand-rolled by craftsmen; the rest of the category consists of machine-made, mass-produced cigarillos, little cigars and filtered cigars, sold in packs of various quantities.

Using nationally representative survey data, FDA investigators have distinguished between premium cigar smokers and those smoking mass-produced products (5,6). They estimated that 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made cigars in 2014 (5). Smokers of premium products make up only 14-20% of all cigar users (5,6). Furthermore, only 7% of premium cigar smokers are daily users, compared with daily use by 22-37% of smokers of mass-produced products. Premium cigar smokers light up less than 2 days per month, and only 30% also smoke cigarettes. In contrast, mass-produced cigar smokers light up 1-2 weeks each month, and 58-66% smoke cigarettes. (5)

In another study FDA staff differentiated primary cigar smokers, who never smoked cigarettes, from two other groups: secondary cigar smokers who are former smokers, and dual users of both cigars and cigarettes (7). In that study, primary cigar smokers made up just over 40% of the 462 cigar smokers, while the other two groups comprised almost 60%. This is important because extensive cigarette use by the latter two groups, compounded by the likelihood that they smoke more and inhale more, likely raises their

health risks. Although this FDA study did not precisely describe smoking patterns, primary cigar smokers use fewer products (average 1.5 cigars on days smoked) and smoked fewer days, compared with secondary and dual users.

Health Effects of Cigar Smoking

The vast majority of cigar smokers are men (5), so it is best to focus only on men when discussing epidemiologic studies.

Usage patterns are important as we look at the health effects of cigar smoking. First, some basic principles. When you burn tobacco and inhale smoke, you consume nicotine and about 7,000 other chemicals. A 20- to 30-year career involving 10 deep puffs per cigarette and 20 to 40 cigarettes per day builds high risks for cancers, circulatory diseases and emphysema. The risks of cigarette smoking are proportional to the amount of smoke inhaled and the duration (years, decades) of exposure, and the death toll from cigarette smoking is high. Every year, 440,000 adults die from smoking-related diseases. For the past 50 years, the American cancer "epidemic" has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.

While cigar use involves burning tobacco, puffing on one or two cigars occasionally or even daily is not the same as deeply inhaling smoke from 20 or 30 cigarettes per day. One would therefore expect that cigar smokers, especially the primary group, would have lower health risks than cigarette smokers. That is in fact documented in a 2015 study authored by FDA staff (4).

For that report, FDA staff reviewed 22 epidemiologic studies on cigars and health outcomes, and they documented all causes of death and many smoking-related diseases. I will focus on the results for **men who are primary cigar smokers, that is, cigar smokers who had no history of cigarette use**. I will use the term relative risk (RR), which you can view as a multiplier. If a group of men who are cigar smokers has an RR=2 for a particular disease, it means they have twice the risk as the referent group of nonusers. An RR=1 is no risk at all. All RRs are accompanied by a 95% confidence interval, which is the generally accepted measure of statistical significance for epidemiologic results. If that range includes 1.0, the result is considered not statistically significant.

To start, let's look at mortality for all causes of death. The first column of Table 1 shows that cigar smokers generally have elevated risks. While most studies do not report the number of daily cigars consumed, two studies (Kahn and Shanks) do. Those results are seen in the second column. Smoking one to two cigars per day had minimal to no risks.

Similar results are seen in the FDA study for various diseases related to smoking, including cancers, heart and circulatory diseases and emphysema. Table 2 shows risks for cancer among smokers of one to two daily cigars. For stomach, pancreas and bladder, elevated risks are minimal and/or based on very limited data. While some risk estimates are elevated, especially for parts of the body in contact with smoke, such as mouth/throat,

esophagus, larynx and lung, none are statistically significant. The risks for larynx cancer are based on only two deaths in the Shanks study and one death in the Shapiro study, which is why the confidence interval indicates that they are not reliable.

Table 3 contains the FDA results regarding cigar-related circulatory disease and emphysema for men who smoke one or two cigars a day. **There were no significantly elevated risks for death from coronary heart disease, stroke or emphysema, which are three big killers of cigarette smokers**. Aortic aneurysm – a bulge in the heart's main artery – was the only disease that was elevated in men who smoke 1-2 daily cigars. It is a serious disorder but a distinctly uncommon cause of death; the mortality rate due to aortic aneurysm among those 45 and older dropped precipitously from 16 deaths per 100,000 in 2000 to 7.4 in 2014.

A follow-up mortality study of 1,139 current cigar smokers, as well as 1,177 pipe smokers, identified in U.S. Census Bureau surveys in 1985 and 1992-2011 was published by FDA staff last year (8). They divided cigar and pipe smokers into daily and non-daily groups. The results, summarized in Table 4, show that some diseases were elevated in daily cigar smokers. However, the Census Bureau surveys did not collect information on number of cigars smoked, so it is likely that the higher risks were among secondary cigar smokers and dual users who are more likely to smoke little cigars and cigarettes in higher quantities. Importantly, nondaily cigar users, who are more likely to smoke premium cigars, had no elevated risks.

The Takeaway Message for Cigar Smokers

Puffing or inhaling the smoke of burning tobacco is not without risk.

The FDA, which now regulates tobacco products, seems inclined to treat cigars the same as cigarettes. FDA staff wrote in their cigar study that "...cigar smoking carries many of the same health risks as cigarette smoking...We have observed that some risks associated with cigar smoking can be as high or higher than those associated with cigarette smoking, especially at the highest doses and levels of inhalation for cigar smoking."

All tobacco consumers in the U.S. deserve truthful information and guidance. The sweeping FDA indictment ignores scientific evidence and misleads cigar smokers. It also ignores the important epidemiology principle that the level of risk is related to the level of exposure. In other words, harm is based on (1) how many people smoke; (2) how frequently and how many products are smoked; (3) the degree to which smoke is puffed and/or deeply inhaled. The following facts are indisputable with respect to cigars: (1) the prevalence of cigar use in the U.S. is extremely small, especially for premium cigars; (2) these products, especially premium category, are used infrequently and in small numbers; (3) they are puffed, rather than inhaled.

The agency's unsupported position has led to needlessly subjecting cigar and pipe smokers, and the manufacturers of those products, to the same onerous and burdensome regulatory regime as much more hazardous cigarettes. Low prevalence, infrequent use

and reduced exposure translates into minimal harm at the population level. Epidemiologic analysis from FDA staff indicate that **consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.**

When Congress gave the FDA regulatory authority over tobacco products in 2009, it did not require that the agency treat all tobacco products as equally hazardous. Unfortunately, the FDA's regulatory actions have done just that, despite numerous scientific studies demonstrating that the risks from smoke-free tobacco (smokeless tobacco and e-cigarettes) are a tiny fraction of the risks of cigarette smoking, and despite the FDA's own study demonstrating that the risks of moderate cigar smoking are significantly lower than cigarette smoking.

The FDA's unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. For all products other than cigarettes, the number of users is low, the adverse health effects are uncommon, rare or nonexistent. Thus, the impact of strict FDA regulation of these products will be inconsequential. The FDA's current posture wastes government resources, undermines public health and does nothing to address the 500,000 annual deaths caused by cigarette smoking.

Table 1. Relative Risk, RR (95% Confidence Interval) For All-Cause Mortality Among Men Primary Cigar Smokers

Study, year	All Cigar Smokers	Cigars per day	
Best, 1966	1.06 (0.92 – 1.22)		
Kahn, 1966	**1.10 (1.05 – 1.16)**	<5	1.04 (0.98 – 1.11)
		5-8	**1.17 (1.06 – 1.29)**
		8+	**1.49 (1.24 – 1.77)**
Cole, 1974	1.15 (0.70 – 1.90)		
Carstensen, 1987	**1.39 (1.16 – 1.65)**		
Lange, 1992	**1.60 (1.30 – 2.00)**		
Ben-Schlomo, 1994	0.48 (0.25 – 0.93)		
Shanks, 1998	**1.08 (1.05 – 1.12)**	1-2	1.02 (0.97 – 1.07)
		3-4	**1.08 (1.02 – 1.15)**
		5+	**1.17 (1.10 – 1.24)**

Bold indicates statistically significant elevation compared to never smokers.

Table 2. Relative Risks (95% CI) for Mortality From Cancers Among Men Smoking 1 or 2 Cigars Per Day

Cancer	Shanks, 1998	Shapiro, 2000	Other Studies
Mouth/throat	2.12 (0.43 – 6.18)	0	
Esophagus	2.28 (0.74 – 5.33)	1.80 (0.60 – 5.00)	
Stomach			1.68 (0.95 – 2.97)[1]
Pancreas	1.18 (0.69 – 1.89)	0.60 (0.30 – 1.40)	
Larynx	6.45 (0.72 – 23.3)	6.00 (0.70 – 53.5)	
Lung	0.90 (0.54 – 1.66)	1.30 (0.70 – 2.40)	1.14 (0.59 – 2.00)[2]
Bladder	0.78 (0.29 – 1.71)	0	

[1] Jacobs 1999, 1 cigar per day.
[2] Kahn 1966, fewer than 5 cigars per day.

Table 3. Relative Risks for Mortality From Circulatory Diseases and Emphysema Among Men Who Smoke 1 or 2 Cigars Per Day

Disease	Shanks, 1998	Other Studies
Coronary heart disease	0.98 (0.91 – 1.07)	1.00 (0.90 – 1.10)[1] 1.18 (0.76 – 1.82)[2]
Stroke	1.01 (0.88 – 1.17)	
Aortic aneurysm	**1.82 (1.11 – 2.81)**	
Emphysema	1.39 (0.74 – 2.38)	

[1]Kahn 1966, fewer than 5 cigars per day.
[2]Jacobs 1999, 1 cigar per day.
Bold indicates statistically significant elevation compared to never smokers.

Table 4. Relative Risks for Mortality Among Daily and Nondaily Exclusive Cigar Smokers[1]

Disease	Daily	Nondaily
All Causes	**1.22 (1.04 – 1.44)**	1.12 (0.82 – 1.53)
Smoking-related cancers	**1.80 (1.20 – 2.69)**	1.08 (0.45 – 2.61)
Lung cancer	**4.18 (2.34 – 7.46)**	0.74 (0.08 – 7.26)
Cardiovascular diseases	1.12 (0.83 – 1.52)	1.20 (0.67 – 2.15)*
Respiratory diseases	1.86 (0.94 – 3.68)*	0
Emphysema	**3.29 (1.33 – 8.17)***	0

[1] Christensen, 2018.
* Based in fewer than 10 deaths.
Bold indicates statistically significant elevation compared to never smokers.

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Chairman RUBIO. Thank you very much.
Mr. Borysiewicz.

STATEMENT OF JEFF BORYSIEWICZ, PRESIDENT AND FOUNDER, CORONA CIGAR COMPANY

Mr. BORYSIEWICZ. My name is Jeff Borysiewicz, and I'm the President and Founder of Corona Cigar Company, which is a retailer of premium cigars. In 1996, I started Corona Cigar Company as a mail order business operating out of an extra bedroom in my house. With hard work, passion, determination, loyal customers, and a great team of employees, over the past 22 years we have been able to grow Corona Cigar Company into one of the world's most recognized cigar retailers. We own and operate four brick and mortar stores with cigar bars in Orlando and Tampa. We employ over 125 wonderful people.

Running any business is a challenge. There are challenges of making payroll, paying the rent, growing your business, and staying ahead of the competition. However, the greatest threat to my business and to the thousands of other premium cigar retailers just like me is the heavy hand of government regulations being pushed forward by the FDA.

For hundreds of years, America's premium cigar retailers have been a part of our culture. Watch any old Western movie and you will see the iconic wooden cigar store Indian posted in front of the local cigar shop. This is an industry where most retail cigar stores are locally owned and operated mom-and-pop shops. The store clerks and shop owners know their customers by name, and the customers trust the retailer for information on what's the latest and greatest in the world of cigars. But if premium cigars are not exempted from FDA regulations, our industry will definitely shrink and it will even be more difficult for a retailer to survive.

In 2018, the Small Business Administration hosted roundtables to gather feedback about the issues facing businesses across all industries. Fellow premium cigar retailers from five states and seven cities spoke out at these meetings and voiced their concern on how the current FDA cigar regulations, if left unchecked, will cause great harm to their businesses.

Some of the new rules from the FDA leaves one shaking her head in disbelief. For example, if a cigar retailer assembles an assortment of cigars and puts them in a package like a bag and sells this as an assortment or gift pack, the retailer must register as a manufacturer. If a cigar shop owner receives a new brand and wants to give a customer a cigar as a gift because he thinks he might enjoy that brand, he is now breaking the law because of the FDA's sampling ban. If a cigar maker wants to donate cigars to our troops, he can't because of the FDA cigar regulations.

The new FDA regulations require that 33 percent of a cigar box lid to be covered with a health warning label. One of the most beautiful features of premium cigars is the handcrafted wooden boxes that these products are packed in. Some of the cigar box art dates back more than 150 years. People buy cigars to celebrate special occasions, like the birth of a child, a graduation, a wedding, or the return home of a soldier. When you walk into a cigar store, our aisles are adorned with beautiful cigar boxes representing the var-

ious brands. When every cigar box has a huge health warning sticker covering a third of that box, our stores will look like you are walking into a dangerous minefield rather than a beautiful humidor.

If a cigar store has a private label brand that bears the name of the store, the FDA regulation states that all printed and electronic ads carry the same health warnings covering one-third of the ad. So essentially, if we run a full-page ad in, let's say, Golf Digest, we would essentially be paying for one-third of that page to advertise a health warning. This is forced, compelled speech and is currently being challenged in court.

The manufacturer's cost of constituent testing and submitting the FDA's substantial equivalent applications will cause most smaller cigar manufacturers to go out of business. For many brands, the testing alone will cost more than the gross annual sales of the boutique brands. One of the most appealing aspects of the cigar industry is the diversity of our suppliers. This is an industry where literally a cigar maker or tobacco farmer could escape communist Cuba on a raft and start a cigar company in America. This is a true scenario; I've seen it happen. FDA regulations will narrow our manufacturers down to just a few suppliers, big multinational companies that can afford an army of lawyers to navigate the complicated rules of the FDA.

One of the main arguments for FDA regulation of tobacco centers around youth access. As a premium cigar retailer and a father, I can tell you firsthand that kids aren't coming into a cigar shop trying to buy premium cigars. It hasn't been a problem in the past and it isn't a problem now. A recent study by the New England Journal of Medicine that was funded by the FDA proves this with "no discernible percentage of youths frequently using traditional cigars" and less than 1 percent of all youths had ever used a traditional cigar within the last 30 days.

It is important to note that even before the FDA had the authority to regulate tobacco, cigar retailers have been federally regulated by the ATF and state regulated by the Division of Alcohol, Beverage & Tobacco. At any time a Federal, state, or local law enforcement agency can run a sting operation where they send in a minor and attempt to buy tobacco. Premium cigar retailers are responsible vendors and no one wants to sell tobacco to a minor.

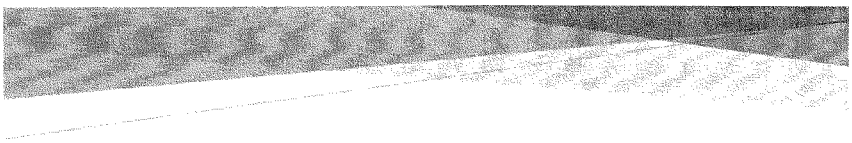
Lastly, I'd like to talk about the impact of FDA regulations on the American cigar tobacco farmer. No other group in the agriculture industry has been hit as hard as the American cigar tobacco farmer. At one time, Florida was the second largest grower of premium cigar tobacco in the U.S. After 150 years of tobacco growing history, the last crop was planted in 1977 in Gadsden County, Florida. In Connecticut, which used to be America's number-one grower of Connecticut Shade tobacco, only one farm is left that still grows Shade. Connecticut and Pennsylvania still grow broadleaf premium cigar tobacco wrappers, but I can tell you firsthand FDA regulations will jeopardize the future of this industry as well, as new cigar blends get harder and harder to introduce and as the industry is forced to consolidate due to FDA regulations. In 2013, we started a small 20-acre cigar tobacco farm in Clermont, Florida to bring back an American farming tradition. However, if

premium cigars are not exempted from the FDA regulations, this too will likely fade away.

In closing, I appreciate the efforts of Senator Rubio, Representatives Kathy Castor, Bill Posey, Gus Bilirakis, and the hundreds of other representatives that have co-sponsored legislation in the past to exempt premium cigars from FDA regulations. However, this issue must get resolved quickly as I am watching a very small industry running out of the financial resources that it takes to fund lawsuits against the FDA, the legal expenses to navigate the existing complicated FDA regulations, and the costs of lobbying in D.C. to save this historic industry.

Thank you.

[The prepared statement of Mr. Borysiewicz follows:]



KEEPING SMALL, PREMIUM CIGAR BUSINESSES ROLLING

Jeff Borysiewicz

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If a cigar shop owner receives a new brand and wants to give a customer a cigar as a gift because he thinks his might enjoy it, he is now breaking the law because of the FDA's sampling ban.

If a cigar maker wants to donate some cigars to our troops, he can't because of the FDA.

The new FDA regulations require that 33% of a cigar box lid are covered with a health warning label. One of the most beautiful features of premium cigars is the hand crafted wooden boxes that these products are packed in. Some of the cigar box art dates back more than 150 years. People buy a box of cigars to celebrate a special occasion, like the birth of a child, a graduation, a wedding or the return home of a soldier. When you walk into a cigar store, our isles are adorned with beautiful boxes representing the various brands. When every box has a huge health warning sticker covering a third of the box, our stores will look like you are walking into a dangerous mine field rather than a beautiful humidor.

If a cigar store has a private label brand bearing a store's name, the FDA regulations states that all printed and electronic ads carry the same health warnings covering one third of the ad. So

when we run a full page ad in a magazine such as Golf Digest, we would essentially be paying for one third of a page to advertise a health warning. This forced, compelled speech is currently being challenged in court.

The manufacturer's cost of constituent testing and submitting the FDA's substantial equivalent applications will cause most smaller cigar manufacturers to go out of business. For many brands, the testing alone will cost more than the gross annual sales of boutique brands. One of the most appealing aspects of the cigar industry is the diversity of our suppliers. This was an industry where literally, a cigar maker or tobacco farmer could escape communist Cuba on a raft and start a cigar company in America. This is a true sinario...I've seen it happen. FDA regulations will narrow our manufacturers down to just a few suppliers, big multinational companies that can afford the army of lawyers to navigate the complicated rules of the FDA.

One of the main arguments for FDA regulation of tobacco centers around youth access. As a premium cigar retailer and father, I can tell you first hand that kids aren't coming into a cigar shop trying to buy premium cigars. It hasn't been a problem in the past and it isn't a problem now. A recent study by the New England Journal of Medicine that was funded by the FDA proves this with "no discernible percentage of youths frequently using Traditional Cigars" and less than 1% of all youths had used a Traditional Cigar with the last 30 days.

It is important to note that even before the FDA had the authority to regulate tobacco, cigar retailers have been federally regulated by ATF and state regulated by the Division of Alcohol, Beverage & Tobacco. At any time a federal, state or local law enforcement agency can run sting operation where they send in a minor and attempt to buy tobacco. Premium cigar retailers are responsible vendors and no one wants to sell tobacco to a minor.

Lastly, I'd like to talk about the impact of FDA regulations on the American cigar tobacco farmer. No other group in the agriculture industry has been hit as hard as the American cigar tobacco farmer. At one time, Florida was the second largest grower of premium cigar tobacco in the U.S. After 150 years of tobacco growing history, the last crop was planted in 1977 in Gadsden County, Florida. In Connecticut, which use to be America's number one grower of Connecticut Shade tobacco, only one farm is left that still grows Shade. Connecticut and Pennsylvania still grow broadleaf premium cigar tobacco wrappers, but I can tell you first hand, FDA regulations will jeopardize the future of this industry as well, as new cigar blends get harder and harder to introduce and as the industry is forced to consolidate due to FDA regulations. In 2013, we started a small 20 acre cigar tobacco farm in Clermont, Florida to bring back an American farming tradition. However, if Premium Cigars are not exempted from from FDA regulations, this too will likely fade away.

In closing, I appreciate the efforts of Senator Rubio, Representatives Kathy Castor, Bill Posey and the hundreds of other Representatives that have cosponsored legislation to exempt Premium Cigars from FDA regulations. However, this issue must get resolved quickly as I am watching a very small industry, running out of the financial resources that it takes to fund lawsuits against the FDA, the legal expenses to navigate the existing complicated FDA regulations and the costs of lobbying in DC to save this historic industry.

Jeff Borysiewicz
President and Founder

CoronaCigar.com
FloridaSunGrown.com
DavidoffTampa.com

Chairman RUBIO. Thank you.
Mr. Newman.

STATEMENT OF DREW NEWMAN, GENERAL COUNSEL AND GREAT–GRANDSON OF THE FOUNDER, J.C. NEWMAN CIGAR COMPANY

Mr. NEWMAN. Thank you very much. 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.

Right here in the Cigar City of Tampa, we proudly roll premium cigars the exact same way that my great-grandfather did 100 years ago, both by hand and by hand-operated, antique machines. We have 136 hard-working and dedicated employees.

Premium cigars are an old-world, handmade craft enjoyed by adults infrequently for celebration and relaxation, and they are just like fine wines. Just as the soil and sunlight and wind and rain can cause a grape grown in California to taste differently than a 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 premium cigars enhances their taste. Many winemakers blend different grapes together to create unique tasting wines. As a cigar maker, we do the exact same thing with premium cigar tobacco. We harness the natural variation in premium cigar tobacco to make interesting blends for low-volume, limited-edition releases. None of this is standardized. None of this is written down. There is no formula. It is not a science. It is an art and tradition that has been passed down from generation to generation to generation.

Premium cigars are just 3 percent of the American cigar industry and are 0.7 percent of the tobacco industry as a whole. We are a tiny sliver of the tobacco world.

We are deeply concerned that the FDA is regulating our small industry out of business by treating our handcrafted, premium cigars like cigarettes.

In 2016, FDA adopted a one-size-fits-all policy for tobacco and applied the same massive and costly regulations developed for cigarettes onto our handcrafted, premium cigars. This approach simply does not work for several reasons.

First, to create a new cigar, FDA requires it to be substantially equivalent to one sold 12 years ago in 2007. The process laid out by FDA is so exhaustive that it is expected to cost $250,000 for a single new cigar. Moreover, the concept simply does not work either, because no two premium cigars are alike, and they change over time. A cigar that was rolled in 2007 tastes different today than it did when it was first rolled a decade ago, just like fine wines mature over time as well.

FDA is requiring us to redesign our packaging to apply massive health warning labels that would turn beautiful stores like Jeff's into walking billboards for compelled speech.

FDA is requiring us to test every new type of cigar. Not only are there no standards or machines or ways for testing premium cigars, but costs so far, at $18,000 per size, are just enormous. This

is particularly a problem because whereas cigarettes are made in large volumes and are standardized, handcrafted premium cigars are made in small batches, just like craft beer.

We are paying thousands of dollars a day in user fees so that FDA can regulate us.

As Chairman Rubio mentioned, current estimates are that it will cost our historic cigar factory here in Tampa around $30 million just to comply with FDA regulations, which is why FDA itself estimated that regulation would force up to 50 percent of the American cigar industry to go out of business.

Unlike Big Tobacco, the American premium cigar industry is made up almost entirely of small family businesses like ours. We sell our premium cigars to 3,000 specialty cigar retailers all 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 the cost of regulation.

In 2009, Congress gave FDA authority to regulate tobacco for two reasons: one, to address youth usage; and two, to address addictiveness. However, FDA's own research has found that children simply do not choose to enjoy premium cigars; and two, the premium cigar consumer, the typical one, consumes 1.7 premium cigars per month. That is not a frequency consistent with addiction.

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

We are extremely grateful to Chairman Rubio and to Congresswoman Castor for their leadership in 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.

Mr. Chairman, 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 125 years.

We are not here today because we want a handout or tax breaks from the government. We simply want the government to allow us to continue this tradition for another 100 years.

Thank you so much for giving us the opportunity to share our story, and we're very grateful. We're happy to answer any questions.

[The prepared statement of Mr. Newman follows:]

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.

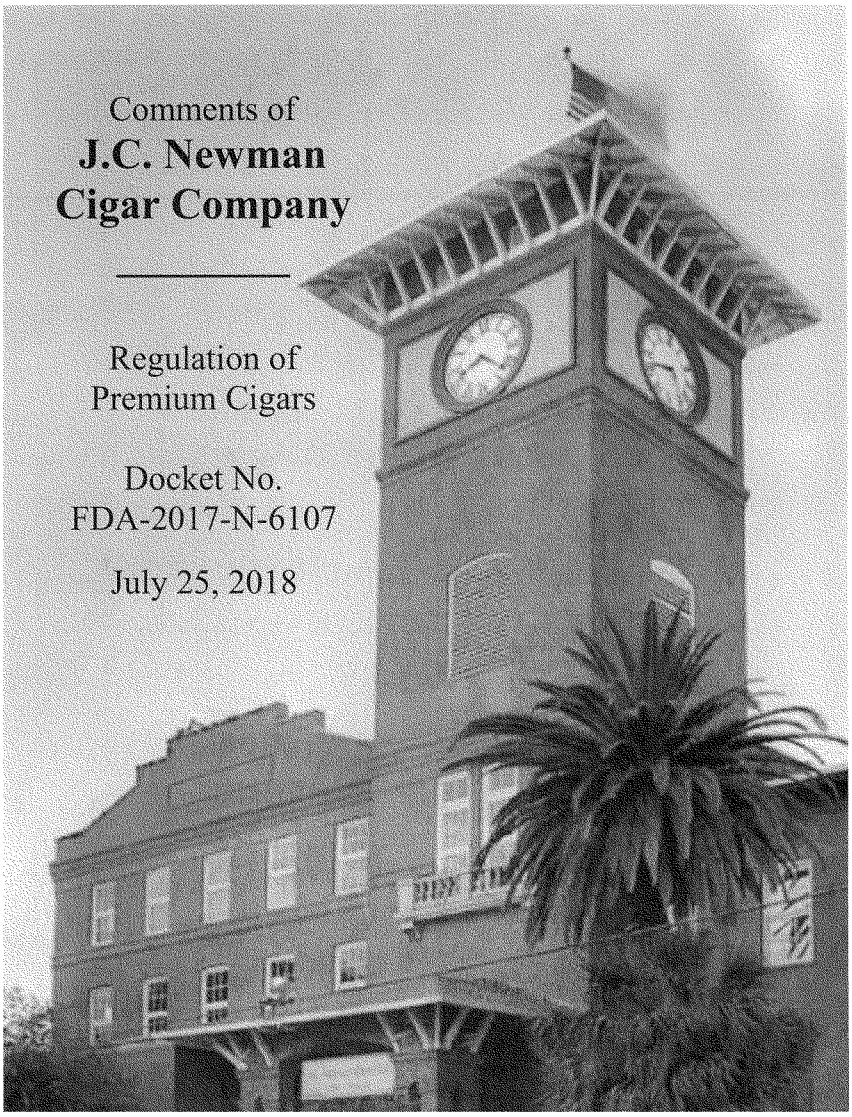

Comments of
J.C. Newman
Cigar Company
Regulation of
Premium Cigars
Docket No.
FDA-2017-N-6107
July 25, 2018

Table of Contents

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"

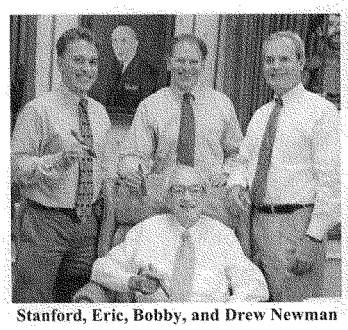
[1] 83 Fed. Reg. 12,901 (Mar. 26, 2018).
[2] *Id.* at 12,903.
[3] Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014," NICOTINE & TOBACCO RESEARCH, 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.

Julius Caeser Newman

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.



Stanford, Eric, Bobby, and Drew Newman

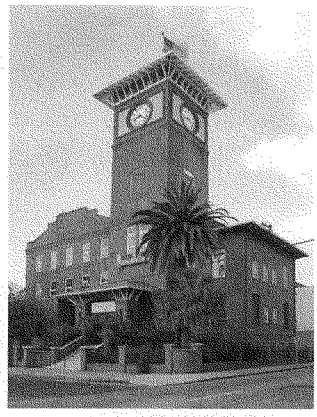
Four generations later and 123 years later, J.C. Newman is still family-owned and operated by Julius's grandchildren and great-grandchildren. Our family business has persevered through two world wars, the Great Depression, the Cuban Embargo, competition from low-wage Caribbean countries, massive federal 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.

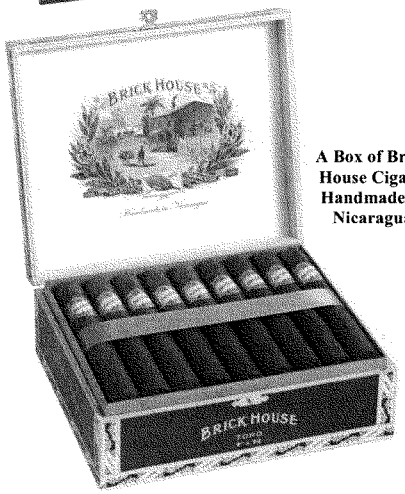
1. They have the same look, feel, smell, and taste.

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.

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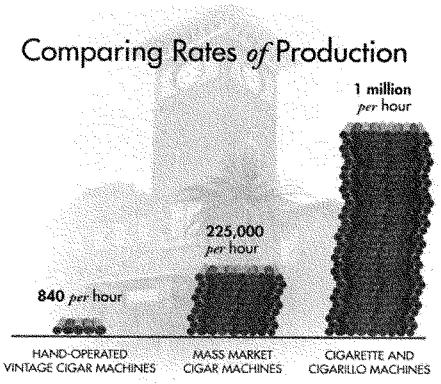
[5] Memorandum from FDA CTP regarding Summary of Write In Campaigns to Docket FDA 2014 N 0189 (Aug. 3, 2015) (emphasis added), https://www.regulations.gov/document?D=FDA-2014-N-0189-82900.
[6] Comments from Charles E. Bailes III (Aug. 11, 2014) (emphasis added), https://www.regulations.gov/document?D=FDA-2014-N-0189-63196.
[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.



2. *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.

3. *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

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[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

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[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

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[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 Americans[26] 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 is 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

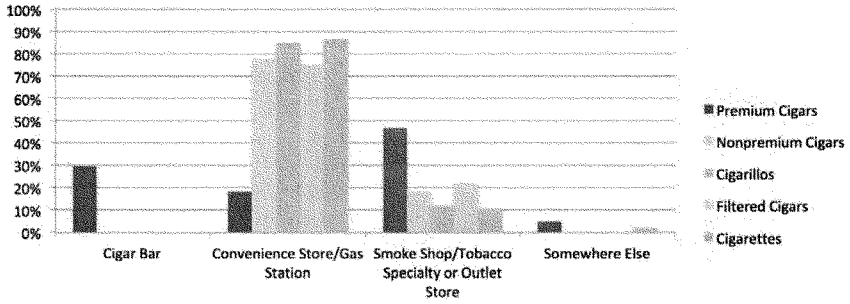
Source: Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014," *Nicotine & Tobacco Research*, at Table 1 (Sep. 15, 2017).

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:

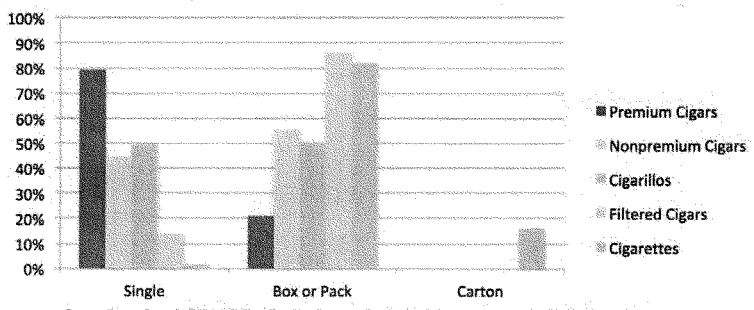
[31] Corey, C., NICOTINE & TOBACCO RESEARCH, at 7. This study also concluded that 93.3% of premium cigar consumers smoked fewer than one cigar per day, slightly lower than the 96.7% reported in 2014.
[32] *Id.*

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



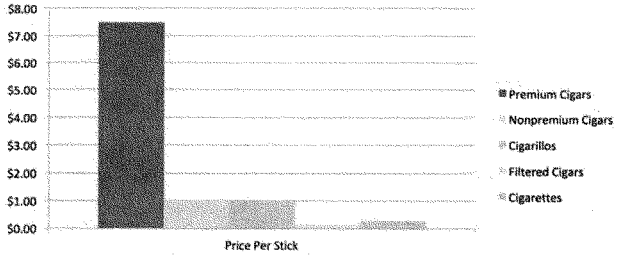
Source: Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the PATH Study, 2013–2014," *Nicotine & Tobacco Research*, at Table 1 (Sep. 15, 2017).

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

		Exclusive Cigar, Nondaily Use	
Outcome	**Number of Deaths**	**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 radio (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	Nonsmoker	Hazard Ratio 1-2 Cigars Per Day	95% Confidence Interval
All causes of death	1.0	1.02	(0.97-1.07)
Cancer of buccal cavity & pharnyx 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	Bobby Newman	Drew Newman
President	Executive Vice President	General Counsel
Grandson of the Founder	Grandson of the Founder	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

Original Option 2	Modified Option 2 *(Includes J.C. Newman's American Factory)*	Explanation
(1) Is wrapped in whole tobacco leaf;	(1) Is wrapped in whole tobacco leaf;	Same.
(2) Contains a 100 percent leaf tobacco binder; (3) Contains primarily long filler tobacco; (4) Is made by combining manually the wrapper, filler, and binder;	(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** (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;	Same as the original (2), (3), and (4). 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.
(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;	(3) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;	Same.
(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);		Because of a wide range of state tobacco taxes across the country, a retail price element is unworkable.
(7) Does not have a characterizing flavor other than tobacco; and	(4) Does not have a characterizing flavor other than tobacco; and	Same.
(8) Weighs more than 6 pounds per 1000 units.	(5) 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 Caeser 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 Caeser 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 Caeser 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,

Craig P. Williamson

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 Caeser 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 K. 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.

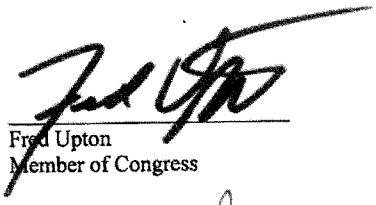
Sincerely,

Kathy Castor
Member of Congress

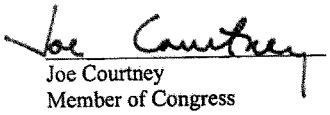
Dennis A. Ross
Member of Congress

Gus M. Bilirakis
Member of Congress

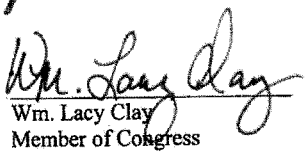
Alcee L. Hastings
Member of Congress



Fred Upton
Member of Congress



Joe Courtney
Member of Congress



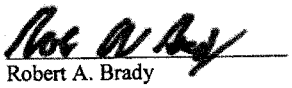
Wm. Lacy Clay
Member of Congress

Ileana Ros-Lehtinen
Member of Congress

Eddie Bernice Johnson
Member of Congress

John Shimkus
Member of Congress

Dina Titus
Member of Congress



Robert A. Brady
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

306 E. Jackson St., 1N • Tampa, Florida 33602 • (813) 274-8251 • FAX: (813) 274-7050
TampaGov

Attachment G

Letter from the Hillsborough County Commission

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.

(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,

Sandy Murman

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

Attachment H

Letter from the Greater Tampa Chamber of Commerce

GREATER TAMPA CHAMBER OF COMMERCE

VISION 2026 #VISION2026

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,

Bob Rohrlack

Bob Rohrlack
President & CEO, Greater Tampa Chamber of Commerce

Chairman RUBIO. Thank you.

Thank you all for being here.

I'm going to recognize Congresswoman Castor for her questions.

Representative CASTOR. Thank you, Mr. Chairman.

Thank you all for your testimony today.

For Mr. Newman and Mr. Borysiewicz, how many jobs are at stake here? You're running a factory, and I've met some of the hard-working employees, many who have been employed there for how long?

Mr. NEWMAN. Our average age—we have 103 employees here in the Cigar City of Tampa. Their average age is 49, and the median tenure is over a decade. We have long-term employees, and they're like a family to us. We're a family business, and that's how the cigar industry here in Tampa has developed over the last 100-plus years.

Mr. BORYSIEWICZ. For us, we have 122 employees, and we have fellow retailers all across the country, and I think that's an important part of this, that this is a national issue. My colleagues are as nervous as I am, whether you're in New York or California or Washington. The path forward, we can see that the path forward is a long-term—it's just going to clamp down on this industry where long term it's going to wither on the vine, it's going to go away.

I think it's important to note, this industry back in the '70s had a big problem too where it was very small. Because the product is not addictive, it's an industry that can get squeezed out of business very easily.

Representative CASTOR. Thank you.

Chairman RUBIO. Congressman Bilirakis.

Representative BILIRAKIS. Thank you.

Mr. Newman, you mentioned in your testimony there is no scientific basis for FDA to regulate premium cigars. If you could elaborate, I'd appreciate that.

Mr. NEWMAN. Sure. Thank you very much, Congressman.

FDA's mandate in the Tobacco Control Act was to address youth usage and to address addictiveness, and FDA's own research on patterns of use for all tobacco products shows that there is use by children of other tobacco products. However, FDA's own research has shown there is an insignificant use of premium cigars by children.

We know this anecdotally as cigar makers, but to have FDA's own data showing that kids don't smoke cigars we think is very powerful. And then on top of that, Dr. Rodu's research that he mentioned showing that the health effects of premium cigars are limited and vastly different than cigarettes, in large part because our typical consumer smokes 1.7 premium cigars per month for celebration, relaxation, weddings, birthdays. It's just a very different approach.

So the FDA's decision to take a one-size-fits-all policy for tobacco products simply doesn't work for our handcrafted premium cigars.

Representative BILIRAKIS. Thank you very much.

I thought we were taking turns. Oh, she's leaving?

Chairman RUBIO. Yes, she had to depart. She had another event.

Representative BILIRAKIS. Oh, okay. Go ahead. You go, and then I'll go again.

Chairman RUBIO. No, no, go ahead. I have to be here until the end.

Representative BILIRAKIS. Okay, very good.

Again for Mr. Newman, we all recognize the issues with youth access to tobacco products and would like to work with FDA and other stakeholders to curb youth access, and I understand the age is 18, as the Senator said, and the legislature is thinking about 21.

Who is your typical customer? Again, you did say this. You may want to elaborate, if you'd like. How does their behavior differ from non-premium cigars?

Mr. NEWMAN. Thank you, Congressman. You know, the FDA has done some really tremendous research on adult and youth tobacco users, and the FDA's own research has shown that the typical age that an adult first smokes premium cigars is 24.5 years old. These aren't teenagers. These aren't kids. These are young adults, and that's why there is not a youth access problem with premium cigars, as there may be with other types of products.

Representative BILIRAKIS. Yes, and they're more costly, aren't they, the premium cigars?

Mr. NEWMAN. Absolutely, Congressman. Our typical premium cigar retails for $5, $6, $7, $8 or more, depending upon the state and the tax levels, and they're sold in adult-only premium cigar shops. So from the marketing to the branding to the packaging to how these cigars are put together, they're just completely different than every other type of tobacco product, and we need the FDA to recognize that they're different.

Representative BILIRAKIS. Thank you, Mr. Newman.

Question for Dr. Rodu. Recent studies have shown a dramatic increase in youth usage of e-cigarettes and vaping products—you hear it all the time—many of which come in youth-appealing flavors. This is a real concern.

Do you believe the FDA's inclusion of premium cigars in the deeming rule detracts from its ability to focus on these products?

Dr. RODU. Congressman, no, I don't. I don't. There's clearly increased use of vaping products among teenagers. I actually just downloaded the NYTS, the National Youth Tobacco Survey data last week and published a blog on that use.

It's interesting because the FDA portrays it as an epidemic. However, most kids get tobacco products, not premium cigars but other tobacco products from their social sources, their friends, their family, and others. They don't buy them at retail, and the FDA has been actually obsessed with the youth issue as a retailer's issue.

So, no, they're not buying premium cigars, and there's no issue here whatsoever.

Representative BILIRAKIS. Okay, very good.

Mr. Borysiewicz, in your testimony you briefly touched on the detrimental downstream effects of the deeming rule on other stakeholders like our farmers in Florida and nationally. Could you expand on that? I know that you touched on it, but expand on it. That's very important.

Mr. BORYSIEWICZ. There's a lot of pressure on American tobacco farmers because of cost. It's very expensive to grow cigar tobacco.

It's totally different than cigarette tobacco. It's not a mechanized harvest. It's all hand labor, and it's a long tradition of doing it. In Connecticut they've been doing it over 150 years, as well.

So there's huge external pressure to be able to compete against countries like Ecuador, Nicaragua, Honduras and the Dominican Republic, which are the primary growers of that tobacco.

So as this industry faces the additional costs of FDA regulation, the owners of these companies or the folks in Europe that own the bigger ones, they're looking at ways to cut costs every way they can, and it's a lot cheaper to go ahead and buy wrapper from Ecuador than it is from Connecticut.

So you're seeing these cost-cutting measures, and you're seeing—what's really important on premium cigars is that new brands are critical to this business, and I'll use it in comparison, let's say, to the liquor business. When I was a kid, the popular brands were Seagram's 7, Canadian Club. Those brands, I don't even know if they make them anymore. You have to have new products that continue to keep the interest of the consumer, and if you don't have those new products that are introduced into this industry, you will eventually—it becomes boring and folks just aren't going to come in and buy these different cigars, and there's no opportunity. If you're growing Connecticut broadleaf tobacco and there's no new brands that are ever going to use it, these guys are going to get squeezed out. They're going to get squeezed out because they can't grow it as cheaply as you can grow it in other countries.

Representative BILIRAKIS. Okay, thank you.

One last question for Mr. Maresca. SBA's letter notes FDA's estimates that approximately 90 percent of the entities affected by the regulations are small businesses. We know that. Do you believe if the regulations remain in effect there's likelihood that what remains of the industry could end up consolidated under a few large companies rather than many small entities, as is the case currently?

And again, are we going to get shut out? These big companies might not even want to produce these cigars because they're so expensive under these regulations.

But if you could comment on that, Mr. Maresca, I'd appreciate it.

Mr. MARESCA. We believe that there is that danger. One of the costs that FDA failed to consider was the cost to these small businesses. Even if they could comply with the premarket approval process and the substantial equivalence tests, they generally would have to hire someone from outside, a specialist, attorneys, just to get through the application process. They're not set up to do that. Bigger companies are. They can do that in-house, or they have people on retainer who do that. So, sure, that's a danger.

Representative BILIRAKIS. Thank you very much.

I yield back, Mr. Chairman.

Chairman RUBIO. Thank you.

Let me start first with the industry, Mr. Borysiewicz and Mr. Newman.

First of all, I think somebody cited that the average cigar smoker was smoking 1.7 cigars per month. I think it begs the question, why are they letting that 0.3 percent go to waste?

[Laughter.]

Mr. NEWMAN. It's a great question.

Chairman RUBIO. I just don't know how to smoke right, that's what it is.

[Laughter.]

Mr. NEWMAN. Mr. Chairman, the frequency of cigar usage changes by the season. In the wintertime when it's colder, our consumers smoke fewer cigars because up north it's colder outside——

Chairman RUBIO. And no one will let you smoke inside their house, cigars especially.

Mr. NEWMAN. That's right, that's right.

Chairman RUBIO. That was my second question. How do you achieve that? But I don't know the answer to it either.

But all kidding aside, there was a comment made—maybe I'll start with Dr. Rodu because the comment was made about the uniqueness of this product.

I think one of the reasons why you see a lot of concern— I'm the father of adolescents, and an adult daughter now at 19, and I've seen this phenomenon of vaping. It's caught on fire, everybody is seeing it. It's all over the place. And one of the concerns about it is that it delivers a high volume of nicotine very quickly, and nicotine is addictive, a very addictive substance. And the concern is not the vaping per se, although there's some additives that have been brought into this vaping issue that are problematic, meaning nonvaping material that's been put in there.

But in addition to it is once someone is that addicted to nicotine, they have to find other sources to get the same amount of nicotine, and the concern is that people migrate over to some of the other products, et cetera.

But cigar smoking, does it carry the same risks? We've seen the health outcomes, but what about the addiction aspect of cigar smoking? Because it does deliver, I imagine, a high content of nicotine, but it does so—but not equivalent to 20 cigarettes, or 25 a day.

I want you to comment, is there evidence in the research—did you do research into the addiction portion of it?

Dr. RODU. Yes, there is. To put it simply, there's no better and more addictive product than cigarettes. The smoke's pH and its characteristics for deep inhalation provides a rapid nicotine impact on the brain. There's no better way to deliver nicotine.

Cigars, on the other hand, are——

Chairman RUBIO. Because it's inhaled into the lungs and into the bloodstream, as opposed to cigar smoke where, if you inhaled it into your lungs, you wouldn't last long. It's not a pleasant experience. You hold it in the mouth and you exhale it. You may be consuming, or I should say you may be producing a high amount of nicotine, but it's not going directly into your lungs and therefore into your blood.

Dr. RODU. That's correct. Cigar smoke is puffed, and there is some absorption across the lining of the mouth and upper airway, but it's not nearly the same impact as with cigarette smoking.

Chairman RUBIO. And therefore we don't see—in your expert opinion, if you were just a cigar smoker, that's all you did, and you

smoked two of them a day, or let's say 1.7 a month, would you be a nicotine addict?

Dr. RODU. You know, nicotine addiction is a very difficult concept to define. Our discussion groups, they go around and around about nicotine and——

Chairman RUBIO. So let me ask it a different way, and I apologize. This might be exactly what I'm trying to get at. Could smoking 1.7 cigars a month become a gateway to cigarettes? Is there evidence that cigar, premium cigar smoking becomes a gateway to cigarette smoking?

Dr. RODU. No, not at all.

Chairman RUBIO. Okay. Let me go to the industry real quick on this. The rule was designed to test a product. That's the other hard thing to explain to people who don't understand about cigars, because even within the product there can be great variety, right? So it's not like something that's produced in a factory which is standardized and machine produced and with all kinds of additional artificial additives to sort of make it almost the same. You can open two different boxes of cigarettes, but with the same label you're going to get a very comparable product.

With cigars, you can be buying the same company's brand with the same product, meaning you have the same band on it, but one is from two years ago and one is from this year, and there can be great variety given the fact that it is not a processed product. It is in many ways more like wine, dependent on weather conditions, soil conditions, and every other thing that may have happened in that particular year. I mean, you can explain, both of you I guess, how much variety there is, even among the same box, potentially even in the same year, but certainly across periods of time.

Mr. BORYSIEWICZ. I'll start with that on the growing side, as a grower of premium cigar tobacco. One of the reasons you have variations also is just the position on the plant that the leaf comes off of. That's why I was saying that cigar tobacco harvesting is not mechanized. It's done by hand. It's done the same way it was done 200 years ago. So you can take a leaf off the bottom of a plant; it tastes different than one that comes off the top of the plant.

We have variations just in the field, meaning that if you can have one section of your field that may have better drainage than the other section, these plants have variations in them. And because cigar tobacco is not thrashed, meaning it's not ground up and homogenized, meaning you're not taking tobacco from all over and just kind of shredding it and combining it, there is very much uniqueness in each leaf, and you will have some variation in the cigars.

Manufacturers try to keep it somewhat consistent, but I can tell you there is definite variation, and that's one of the problems the FDA has had when they're trying to test these cigars. They're all over the place, and that's one of the things they can't get their hands wrapped around because they're trying to use the same type of regulations that were designed for cigarettes. Cigarettes do use tobacco that's very consistent because you're mixing thousands and thousands of pounds together, and there's casing what's called, where you add things to the tobacco.

When you take cigar tobacco—I can tell you right now what comes out of our farm, nothing but dried brown tobacco leaves. There's nothing added to it. It's simply moisture and humidity during the day, in the morning that we use so we can pack tobacco, but there's absolutely nothing added to that.

Mr. NEWMAN. Jeff is right. We harness the natural variation to create unique blends, and not only within the same fields and within the same plants is there great variation, but from season to season or crop to crop, depending upon the amount of wind or rain, which give great variances. So with the FDA trying to create a scientific standard and holding our products to a manufacturing—like when somebody manufactures Tylenol, it's just inconsistent because of the extreme natural variation that we use in premium cigar tobacco.

Chairman RUBIO. I'm sorry to inform you but since you held up that cigar, we're going to have to seize it as evidence.

[Laughter.]

Mr. NEWMAN. Happy to submit it.

Chairman RUBIO. We've got to follow the rules.

[Laughter.]

On the testing side, is there such a thing as a standard test to test cigars?

Mr. NEWMAN. Not at all, Mr. Chairman. There's been great science developed over decades for testing cigarettes, and the reason is because cigarettes come in just a couple of standard sizes, and they're consumed the same way.

We make cigars that are long, that are short, this one has a torpedo end on it, some are thicker, some are thinner. There's just an enormous variety in cigars because premium cigars are an all-natural, handcrafted product. So unlike cigarettes, there are no machines to test products like these, and there are no standards for them to address the variability in the size and the length.

An FDA study three years ago showed that there is enormous variation in how much of a cigar a consumer smokes. Some people will smoke half of it; some people will smoke all of it; others smoke an inch. So trying to standardize that in a scientific way to create a rigorous testing regime just doesn't work and hasn't been developed for premium cigars like exists for other types of tobacco products.

Chairman RUBIO. I guess what I'm getting at is, if even within the same brand and product there isn't uniformity the way there is in a mass-produced product, and there doesn't exist a test that can accurately measure these products in general, not to mention because of these varieties, are we talking about a rule that can't even be complied with? Even if you wanted to comply, could you even comply? Could anyone comply with the rules as currently written, unless you went to machine-produced cigars?

Mr. NEWMAN. You're absolutely right, Mr. Chairman. There's no way to comply with the rule as developed. My grandfather used to tell me that the reason why we've been in business so long is because we get along, we follow the rules, we don't take any shortcuts, and if there was a way for us to comply, we would do our very best to comply. But what keeps us up at night is that the FDA is imposing requirements on us that we have no way of being able to

comply with, and that's what's so scary about the FDA regulation on premium cigars.

Chairman RUBIO. I guess the way you both described it, it's apparent that both the cost and complexity of compliance means that the small businesses that largely comprise this industry, that there is no way that they would be able to comply with this. So to the extent that the industry—I'm sorry; you were going to add?

Mr. BORYSIEWICZ. Yes, I want to add to that, because one of the interesting things that I've seen as a retailer, when I talk about the big multi-national companies that have an army of lawyers and the funds to do this, they have submitted what the FDA is requiring, and there's a very good chance that what they're even submitting—because the FDA's testing does not work. So what happens is the smaller companies that could never afford to do this anyway—these guys are sort of in limbo right now, and it's literally their business—they're taking it a day at a time. And there's a lot of folks that look at this saying, you know what, there's always good versus evil and things kind of work out, and they just feel like there's no way that we're going to be put out of business by this rule because it's just so unfair, it's just so undeserved. And a lot of folks are like Congress is going to save us, somebody is going to step in because this is so wrong what's being done.

But I'm afraid that—I will tell you one of the quotes that I heard when I was up in D.C., is that Congress doesn't work that way. Generally they start needing to see businesses go out of business before they see something is wrong. There's the famous words of unintended consequences, and I can tell you what's happening. The unintended consequences in this business are going to be the little guy sitting here in Ybor City that has three cigar rollers, the guy that's got a place in Miami that has 15 rollers. It's all these little guys that are going to be the unintended consequence, and we've got to fix this because it's just not right.

No one came to this country, or no one started a business thinking they were going to lose it because of the United States Government, and that's exactly what's happening right now, that's what's going through everybody's mind. The government is not supposed to be the enemy of a small business, or of any business.

Chairman RUBIO. So, who will be in business? Are products that are made abroad covered by this?

Mr. BORYSIEWICZ. I'll answer the question. The guys who will be in business are the ones who have the deep pockets, the ones that can figure this stuff out. Listen, when you even read what is required—I mean, I'm educated, but I read what the FDA is asking, and I don't understand it. Half of our industry doesn't understand it. We have trade association meetings and we ask questions: Well, what does this regulation mean? What does this do? Just last week the FDA put out another rule supposedly clarifying the other one that no one understood.

[Laughter.]

Nobody figures this out. They don't even know what's going on. So what's happening is you're trying to run a business and you keep saying in your head, do you invest the money in this factory, do you invest the money building this store? Imagine trying to run

a business when you just don't know what's going on, and that's the biggest problem that's facing us.

Chairman RUBIO. As you understand it, or the general counsel for a company, the products that are being manufactured abroad, will they have to meet the same regulation?

Mr. NEWMAN. They will eventually. The regulation process is being phased in. Domestic manufacturers right now are required to register their brands and report ingredients. Those requirements have not yet been extended to foreign manufacturers yet. So the FDA, in effect, has a higher standard for domestic American small businesses making premium cigars than it has on foreign factories.

Mr. BORYSIEWICZ. I want to add to that, though. There is a little bit of a curve ball in the sense that if the embargo were to end with Cuba, and if Cuban cigars were brought into the United States, none of those were on the market before 2007, so none of those are grandfathered cigars. The question is whether they can get through the premarket approval process, which is what a lot of the biggest problem is.

So what I think, if the embargo were to end today, the way the FDA regulations are, those brands, I don't see how they can even enter the country because they haven't registered with the FDA and are not a grandfathered brand.

Chairman RUBIO. So, in essence, there would be no premium—unless someone is willing to undertake this price and go through that, there would be no premium cigar industry in the United States. It would become almost a contraband product.

Mr. NEWMAN. I think so, Mr. Chairman. We're such a tiny industry. As you pointed out, we're 0.7 percent of the tobacco industry in America right now. It would be very easy for the bureaucracy in Washington just to smoosh us like a bug.

Chairman RUBIO. All right. I want to get real quick to the health part of it. Let me ask you, Mr. Maresca. I'll start with this. Did the FDA work with the Office of Advocacy prior to finalizing the regulations?

Mr. MARESCA. Prior to the publication of the Notice of Proposed Rulemaking in 2014, we had minimal contact with the FDA.

Chairman RUBIO. I'm sorry. Minimal?

Mr. MARESCA. Minimal.

Chairman RUBIO. So what data did you provide them when you ultimately did have that contact?

Mr. MARESCA. The most information we were able to provide FDA was in our comment letter. We have offered the resources of our office since that time to help the agency acquire data and help the agency to use that data in any future rulemaking. That's the extent of our contact.

Chairman RUBIO. Do you have any indication that the FDA considered the feedback that you provided?

Mr. MARESCA. I think the rule speaks for itself, Senator. The agency declined to exempt premium cigars even though they did suggest that they were considering exempting premium cigars.

Chairman RUBIO. So while the FDA's proposed rule considered exempting premium cigars, the final rule suddenly included them. As an expert on regulation, do you think this proposed rule provided adequate notice to the industry that was affected by the rule?

Mr. MARESCA. Well, it's a unique industry, as you know, and as Mr. Borysiewicz said, many people in the industry relied on FDA or somebody to save the industry. I don't think that the notice was quite enough, and I think many in the industry, especially many smaller members, were led to think that they were not going to be regulated.

Chairman RUBIO. On the health care aspect, I'd like to go back to that. On the health cost of it, I guess 0.7 percent of all smokers are premium cigar smokers. Of that amount, only 7 percent of that small less than 1 percent of all smokers, only 7 percent of that amount are daily users, meaning one or two a day.

So if you can just repeat what you went through in your testimony, what do we know about the health impacts of someone who smokes cigars, not concomitant with cigarettes or other products? Do we have information on that subset and what the health impacts are?

Dr. RODU. One of the problems with studying a very rare behavior is that you don't have large numbers, so you have to combine populations from many different places. That's been done to a certain extent, and yet the results of those studies have not found any or hardly any significantly elevated risks among those cigar smokers. So the public health impact of low prevalence and low disease risk is miniscule.

Chairman RUBIO. In your opinion, are the numbers we know about that user, if any other product on the market didn't involve the word "tobacco," would it be something that we would be regulating given the figures that you're seeing?

Dr. RODU. Not a chance.

Chairman RUBIO. Then I would imagine that if the numbers are negligible among daily users of the product, which represent a very small sliver of a very small sliver of all smokers, it would stand to reason or perhaps the data says that people that smoke less than once a day, including the average 1.7, to the extent this product causes harm—it's scientifically valid to argue that if something is harmful, the more you use it, the more harmful it is. The people who are smoking less would be having less of a problem?

Dr. RODU. In my review of the FDA study, I found virtually no impact from one to two cigars per day. That's what they defined as the lowest cigar consumption. If you smoke higher numbers, yes, the risks tend to go up somewhat. But at one to two cigars a day, there was virtually no health impact. So smoking less is going to be essentially not measureable.

Chairman RUBIO. Let me ask you, are there differences in health outcomes between premium cigar smokers that have never smoked cigarettes and those who have?

Dr. RODU. Generally speaking, the data is not that detailed.

Chairman RUBIO. So we don't have the detail. My sense of it is that, as noted in your testimony, 40 percent of premium cigar smokers have never smoked cigarettes. So the notion that you have a significant percentage of this, again, very small sliver of a very small sliver, it's not a supplement to their cigarette smoking. It's a unique habit unto itself.

Dr. RODU. That's correct.

Chairman RUBIO. Do you have anything else?

Representative BILIRAKIS. Well, again, the basic question is give me a definition. I know that we know. But, first of all, a definition of a premium cigar. And secondly, go through the process, what does it take to produce a premium cigar as opposed to a non-premium cigar, and the cost process as well. And why do folks only smoke two a day, as opposed to a pack of cigarettes a day? Is it the cost solely? Give me your opinion on that.

Mr. NEWMAN. Thank you, Congressman. Well, to your first point, I think the universally agreed upon definition of a premium cigar is in Senate bill 9. It's in Chairman Rubio's bill that defines the premium cigar as a handcrafted product. But we roll cigars today just like my great-grandfather did 100 years ago, and one of the reasons why our consumers smoke so few of them is because they use them for relaxation and for enjoyment, whether playing a round of golf or going fishing or in a fire pit in the backyard.

We live in such a fast-paced world these days, Congressman, with this hearing being live-streamed over the Internet, that a premium cigar is one of the few things you can light up and enjoy just for relaxation. You can't rush enjoying a cigar. You've got to sit down and be able to just take a few minutes and slow down and relax, and it's a great way to do that. But our consumers, given the hectic pace of life these days, can't do that every hour, every day, every week. It's an infrequent enjoyment.

And something else that I really appreciate about premium cigars is that they transcend all barriers. If you walk into one of Jeff's shops and you pick up a handcrafted premium cigar, and you sit down and light it up, it doesn't matter your race, your age, your background, your education, your religion; everyone is friends. It's a social relaxation tool. It's a way to slow things down.

And the fact that this is a handcrafted product on the team in your field, Jeff, who plant the tobacco and grow and harvest it and actually cure and age and ferment and sort it and roll it and band it and box it, from start to finish, it's all handcrafted, and there just aren't many things left in the world like that anymore, and that's what makes premium cigars, I think, so special and what a great thing to have, to be able to continue this tradition for relaxation and celebration.

Representative BILIRAKIS. Okay. Let me ask Mr. Borysiewicz, are you in the business of non-premium cigars as well?

Mr. BORYSIEWICZ. No, and that's a great question because there are two categories. The large category is volume of cigars, what are called mass-market cigars. That's the term in our industry. Mass-market cigars are the ones you see in the convenience stores, drug stores, usually two in a foil pack. Those don't require humidification. You don't have to cut the end off of it. It's not a natural wrapper on the outside. The outside of that leaf is what's called homogenized tobacco, meaning it takes—it's sort of like when you make paper out of wood pulp, except you're making the wrapper out of tobacco instead of paper.

So those cigars that are sold in those convenience stores and drug stores, that's a big part of the industry when you use the general word "cigar."

Premium cigars are the ones that are sold typically by your tobacconist in your neighborhood cigar shop. They require to be hu-

midified. You need to keep them in a humidor, use a cigar cutter to cut the end. They burn usually for 45 minutes to an hour-and-a-half. They burn real slow, and the reason being is that the wrapper is a whole leaf of tobacco. When I talk to you about why it's so expensive to grow tobacco that goes on the outside of the cigar, let me tell you, as a farmer it is extremely hard to grow a leaf and get it through the entire process where a bug doesn't eat a hole in it, where someone doesn't put a finger through the wrapper, or it doesn't have a stain on it.

So the wrapper is the most expensive part of the cigar, and that's what we call a natural leaf wrapper. It's literally a piece of leaf that's wrapped around it. So when you go into a cigar shop, we sell only premium, handmade cigars. The folks that walk in—first off, you can't compete anyway with a 7–11 or something like that that sells the mass-market cigars. That's a totally different industry. So we're selling premium handmade cigars. What I think is interesting is it's two totally different customers, two totally different experiences, and two totally different prices.

Representative BILIRAKIS. What about the health risks? Are they the same? Anyone can answer that.

Mr. BORYSIEWICZ. The other thing is that size is important, too. So one of the phenomena that happened in the industry, they have these filtered cigars too. They're classified as little cigars in the filtered cigar. That's a different product too that is not the same as what we call premium cigars. You don't inhale a premium cigar, and they're just totally smoked for different reasons.

Dr. RODU. It's really not about the smoke. It's about how they're used. Disease risk is based on dose—that is, how much you consume—and duration, how long you do that. Premium cigars are just consumed in an entirely different manner than machine-made cigars and manufactured cigarettes.

Mr. BORYSIEWICZ. There's one more clarification I'd like to bring up, too. The mass-market cigar category is not driven by new brands as much as the handmade cigar. If you walk into our cigar store, I literally have over 1,000 different brands, over 1,000. So when you walk into a 7–11 and you look at the slots where the mass-market cigars are, you might see 25. So it's a totally different industry. And of the 25 of those mass-market cigars, they're generally produced by three companies.

So that's why I say those guys have the resources and the lawyers and everything else to work through that. I mean, they still have issues to work with the FDA, but it's totally different when you're looking at an industry that sells billions of units and there's the money that they can handle regulation. The big difference is the premium cigar industry is tiny and it cannot handle it financially, and honestly they can't figure it out.

Chairman RUBIO. That's important. I'm sorry to interject, but the products you just described is what you'd see at a gas station, right? I mean, I've seen some gas stations that have the humidor, but you're talking about the gas station that has a box with three or four what look like cigars, long and thin. I don't want to attack any brand, but Dutch Masters or something like that, these little things that are out there that are mass manufactured, people may think that's what we're talking about here.

Mr. BORYSIEWICZ. That is not what we're talking about.

Chairman RUBIO. What we're talking about here is the premium cigar that is sold either as a unit in a box or individually in a cellophane wrapper. These are the practical things about cigar smoking. If you're not a cigar smoker, you don't know. Number one, the time it takes. It does not lend itself to quick usage. I mean, it's not like a cigarette that's done in X number of minutes. You can't just go out on the corner and puff a cigar. Depending on the cigar, and depending on how often you puff on it, it could take anywhere from 35 minutes to an hour-and-a-half, if you're doing it the right way.

Second, these things have to be stored. You can't just put them in a box or put them in your pocket. If they're not stored, over time, because they're a natural product, it dries out. You can't leave them in your car. Not everybody has to have one of these expensive humidors, but you can't just leave this stuff laying around. So there's care involved in it.

And that's why I wanted to ask. In your time just in the retail side, when was the last time you had someone 17 or 16 years old come in and try to buy a box of premium cigars for themselves?

Mr. BORYSIEWICZ. I would say it's never happened. For example, this box of cigars right here is $250, okay?

Chairman RUBIO. We will have to seize that as well, by the way.

[Laughter.]

Mr. BORYSIEWICZ. If you're a kid, do you want to spend $20 on Fortnight or whatever these guys are playing, or do they want to go try to buy a premium cigar?

I'll tell you the other thing that's true, especially in our cigar stores. We have such a great group of folks that enjoy these cigars, they come from all walks of life. If you're a college graduate, sure, go put your profile on LinkedIn. But you know what? Go hang out at the cigar shop, because you're going to meet some real interesting people there. These are folks that own businesses. These are folks that are politicians, industry leaders, community leaders.

I run Corona Cigars. This is a very interesting phenomenon that we do, that if a child were to see their father sitting outside a Corona Cigar store smoking a cigar, that they shouldn't be ashamed. This is an environment where adults are gathering, and I call it the modern-day coffee shop, with the exception that our customers, instead of sitting there with their faces buried in a cell phone or a laptop, they're engaging in the lost art of conversation, and that's what goes on in the cigar shop.

So if you even had a kid that came in, that walked in, looked like he was a kid, chances are there's probably a customer who is going to stop him and say, hey kid, what are you doing in here? It's just not the environment for that. This is not a 7–11 where you're going in to buy a milkshake or whatever, a Slurpee. Cigar shops are a very traditional type of business that cater to an adult crowd, and it's just not attractive to a kid.

Chairman RUBIO. The statistics bear this out, do they not? In studies that were done? Dr. Rodu, they found that among youth, the consumption of premium cigars, they couldn't even score it.

Dr. RODU. That's correct. It's very rare among children.

Chairman RUBIO. You both have been interacting, both from the association and individually from business, with the FDA and the

regulators. All this has been presented to them. What have they said to you as justification for this application? One of the things they cannot argue, in my view, is that they don't have the legislative flexibility to reach a different conclusion. They most certainly do. In fact, the regulation calls for them to provide the appropriate level of regulation, appropriate to the risk of the intention of the law.

How are they—what is their justification?

Mr. NEWMAN. Mr. Chairman, we've had the privilege of meeting with the FDA many times, met with Commissioner Gottlieb and his staff over at the Center as well, and I actually like them, and I like the FDA. They make sure that the water we drink in bottles is safe and the sandwiches we eat are safe, too. And when we've talked to them about premium cigars, we had a senior official tell us, well, you're not the problem, we're not worried about you, but the agency has limited resources, and they've been focusing their resources on other areas, such as e-cigarettes, that are of greater concern to them.

So we've been left in limbo for years waiting for them to just recognize that our issue is serious to us and to America's handcrafted historic premium cigar industry, and we need relief. They just haven't had the capacity or the ability to provide the relief that we need.

Chairman RUBIO. But—oh, go ahead. I'm sorry.

Mr. BORYSIEWICZ. I'd love to add to that, and I don't mean this in disrespect, but I've been dealing with this since 2007. In my opinion, what's going to happen is we're never going to see relief through the FDA, ever. And it's sad, and I'll tell you why.

They understand that we are not the problem. They totally understand that. But you have to look at the end game if you're working for the FDA. What happens when you leave the agency? Who is going to hire you? Big health, big pharma, somebody in that realm is going to hire you, a drug company. It will ruin your resume if you are the head of the FDA and you exempted premium cigars.

I believe that is our biggest challenge, and that's why we have to have somebody from the business sector, whether it's OMB, Small Business, Congress, that weighs in and says listen, this has to be fixed, because I think if we leave it up to them, we're kidding ourselves. That's just my take on the situation.

I've been in many of those meetings. They understand what we're doing. They understand what they're doing is—they're having a hard time with this. I'm telling you right now, they can't figure it out. That's why they're re-issuing these rules.

I met with FDA at one of our trade shows and explained to the lady, who was a senior fellow, by the way, a Ph.D. I took the cigar apart. My wife was with me and we showed her exactly what it is, the definition of a premium cigar, the wrapper/binder/filler, and how they're smoked and everything else, and she was absolutely amazed. As a matter of fact, at the end she said it sounds like I should try a cigar myself, it's very nice.

But I don't believe it's the individuals. I believe it's the system, and that's why we have to have some correction. It's not the individuals, but it's the system.

Chairman RUBIO. What you've described is the legislative impediment, and that is, number one, some of the things we're highlighting here are the reasons why we're having a tough time, and that is the overwhelming majority of Americans are not premium cigar smokers. So what they know about premium cigars is they remember their uncle that used to smoke these or what they've seen in movies.

I had a colleague of mine talk about—made reference to pinky rings. I don't know what that has to do with cigars. I guess he saw some movie where a gangster had a pinky ring smoking a cigar. And my point is that there are a lot of people who just don't understand what the product is.

The second is they don't understand the impact that the rules have, and their view of it is, well, it's just notice that it could be harmful to your health; what's the big deal? I don't think they realize some of the unique attributes of the product. Number one, the testing and all that goes into it. There's nothing you can comply with. What they're actually doing is they're going to leave the whole industry to the people who can comply with it, which is the mass producers.

Number two, part of the overall experience is the packaging, and the packaging is not conducive to having a third of the entire box be some warning label with a skull and crossbones on it, or whatever it may be. Not that people wouldn't buy it. The premium cigar smokers aren't going to walk away, but just doing it, just producing it in that way would be extraordinarily difficult.

So I think our blessing is our curse in this regard, and that is that because not enough people are familiar with the premium cigar industry, they're not consumers of it, it's a unique niche within the broader sector, it's tough to explain it to people. The safe place to be is against anything that has to do with smoking and tobacco and everything else.

And then we have interest groups who do great work on getting people to stop smoking, documenting clearly that cigarette smoking and tobacco consumption of that kind in America is a leading cause of premature death, heart disease, cancer of various types. We know that, and the efforts that have been put forth by many of these organizations have made a tremendous contribution. But many of them feel like there has to be a bright line that they are not willing to cross, even for something as unique as this, because it could be the beginning of a trend to rollback others.

So that's why we continue to believe that the legislative fix reaffirms the true intent of the law, and we've had difficulty because of a handful of our colleagues that have made it controversial. When you're dealing with 1,000 issues a day, it's hard to get people to bear down on this level of detail like what we discussed here.

We're making progress, but it's been difficult. One of the resources we tried to use is both manufacturers and the retail outlets that are in every state in the country, and that have a presence in every state in the country.

We will continue to work on it because I think what you're basically telling us here today is if this rule takes place and goes into effect, there are not going to be any premium cigar manufacturers, if any, left in the United States, and ultimately we're going to have

a product that eventually, the only way to consume it is to somehow smuggle into the United States some product that's made somewhere else where those regulations are not required to be put on, and the outlets, all the retail outlets that sell it, there's no way they can survive. I mean, they won't have any product to sell.

I don't foresee how, not only on the manufacturing side but on the retail side, I just don't know how any of these places survive if this goes into effect. Is that Draconian, apocalyptic vision, is that really where we're headed in your opinion?

Mr. NEWMAN. Mr. Chairman, you're absolutely right, this is what keeps us up at night and worries us. We urgently need relief, and we've been in limbo for so long, and if we don't get relief, the tradition of handcrafting premium cigars here in Florida and America and right here in Ybor City is going to go away like a puff of smoke.

Chairman RUBIO. Well, I want to thank all of you here. We've almost exceeded the time that we promised, but I do want to thank everybody for being a part of this. I want to thank all of our witnesses. It's an honor to chair this committee. I want to thank Congresswoman Castro for coming today. This is her district. I know this is very important to her. She sponsored the legislative fix in the House. And to be fair, the House has actually done this. It's been on the Senate side that we've had some problems, but we continue to work through it. Of course I thank my friend, Congressman Bilirakis, for coming over to be a part of this hearing as well, and to host it here in Ybor City is a very unique place whose entire history is tied around this industry and gives character to this community.

So I'm grateful that all of you were able to make it here today and the contributions that you've provided. Each of your testimonies offered an important perspective. The record that was created by this hearing, people said it was only two Congress members and a Senator, and they're all with us now, so what does it matter. But this record is important. It's what we can point to and we can cite to the staffs of other senators when we make the push again. We put all of this into the Senate record.

We're going to keep working on this. We're not going to let this happen. We're going to do everything we possibly can to prevent this from happening because it's one of those things that no one understands why it's happening but it's happening anyway, and we've got to correct it.

So the record for this hearing will remain open for two weeks in case any of my colleagues on the committee or anyone else on the panel wanted to offer any additional statements for the record, or questions that may come in from members of the committee that were not here today. If they do, we'll forward them to you. We ask you to help us over the next few weeks to answer those questions. We may have some of our own just to get them into the record.

Again, I want to thank all of you for being here, everybody who came.

Do you have anything to say before——

Representative BILIRAKIS. No. I just want to say it's all about education, and what I'll do is I'm on the Energy and Commerce Committee, so we'll try to see if we can get my colleagues to set

up—the Chairman, and also the Ranking Member, to set up a hearing in the House. This is all about education. People want these cigars, no question, and they should have a right to have them. That's all.

Chairman RUBIO. Thank you. Thank you so much.

I ask unanimous consent that the statements for the record here today be submitted.

Since I'm the only one here, there's no objection to that.

[Laughter.]

And with that, the hearing is adjourned.

[Applause.]

[Whereupon, at 2:35 p.m., the hearing was adjourned.]

APPENDIX MATERIAL SUBMITTED

The Boutique Cigar Association of America
8334 SW 193rd Street
Cutler Bay, Florida 33157
Tel # 305-255-6368
Fax # 305-907-5451
www.thebcaa.org

Senator Marco Rubio
284 Russell Senate Office Building
Washington, DC 20510
Phone: 202-224-3041

7400 SW 87th Avenue, Suite 270
Miami, Florida 33173
Phone: 305-596-4224

April 03, 2019

To: Senator Marco Rubio

Re: Keeping Small, Premium Cigar Businesses Rolling

Dear Senator Rubio:

The Boutique Cigar Association of America (BCAA) is an organization that represents small boutique manufacturers/importers of premium cigars in the United States. My name is Dr. Gaby Kafie, I am a licensed physician in the State of Florida and the Founder of the BCAA. I currently do not practice medicine, as I have dedicated my life to the art of making traditional premium cigars. This is what I want to do the rest of my life.

The BCAA was founded less than 3 years ago to represent the interests of small sized boutique cigar makers. The twenty eight member companies that we currently represent are all family owned and operated. Every member company produces 500,000 premium cigars or less each per year. These family owned businesses face the possibility of extinction due to the burdensome "costs of compliance" of the present day FDA regulations facing the premium cigar industry. We estimate the number of companies that exist similar in size to our member companies are far greater than 100 in the United States. Membership to our organization continues to grow on a monthly basis. We consider ourselves the voice of small family owned cigar manufacturers.

The BCAA represents the most vulnerable sector of the premium cigar industry. Each and every member company produces in levels that can be classified as small batch

production based on the availability of tobaccos for our specific blends. Each season such tobaccos change and thus would require even further testing, limiting our ability to not only grow our businesses but also to stay in business. There is little doubt our members could not comply with the pre-market approval and substantial equivalence requirements of the present regulations. No regulatory program set forth by the United States government should threaten the entrepreneurial spirit and very existence of our member companies.

We estimate our member companies employ more than 2500 individuals between Central America and the United States. Our families, our employees, our distributors, and our retailers depend on the traditional premium cigars that we produce. Our manufacturing methods have not changed over the past 100 years, and the same could be said about the all natural air cured and aged tobacco that we use in all of our blends. Introducing new regulations to a traditional industry seems totally contradictory.

As a physician, I wholeheartedly agree that tobacco products should be for adults only. Furthermore, as a physician I firmly believe that premium cigars are in a category to themselves. Premium cigars are not addictive, and furthermore the smoke is not inhaled. It is irrational to think that we are being asked to test a product that is not inhaled. The FDA claims that there are no fees associated with such regulations, but they fail to discuss that the testing performed by private labs will cost a minimum of $10,000 - $20,000 per cigar. On average, the portfolio of a boutique cigar company may have 30 different cigars/offerings to its customers. This translates to nearly $500,000 in testing fees alone, not including attorneys fees for proper filings with the FDA. Such fees are devastating, and will put all family owned boutique cigar companies out of business. There are sufficient studies currently available that compare the effects of cigars vs. other tobacco products, specifically cigarettes. In 2015, an FDA funded report showed that smoking up to two cigars a day is associated with minimal significant health risks. Premium cigars do not pose a health risk to the connoisseurs they are created for (adults of legal age).

As you are well aware, most if not all boutique cigar companies are owned by 1st or 2nd generation immigrant families here in the United States. These individuals work tirelessly to support their families and their staff. We are talking about families who depend on their God given talents and skills to make premium cigars. These are not wealthy people, nor are they able to attain financing for such expenditures (from regulations) moving forward. It is for this main reason that we should seek an alternative path for the preservation of our industry.

None of the companies that are members of the BCAA produce flavored cigars. I know this has been a very controversial subject as it has been stated that flavored cigars are intended to entice minors to begin smoking. That is not the case with all of our BCAA member companies. We all produce all natural dry aged tobacco premium cigars. Our cigars are made and intended to be enjoyed by adults over the age of 21. Studies show that the average age upon which a person picks up their first premium cigar is age 27.

All of the companies that are members of the BCAA sell directly to licensed brick and mortar tobacconists whom specialize in premium cigars. Such tobacconists or cigar lounges have always held very strict age verification standards. In fact, over the past two years the FDA has issued several citations to retailers whom have sold tobacco products to minors, none of which were premium cigar retailers. This says a lot for our industry. It states that our products are made for adults, and enjoyed by adults.

I have always been a firm believer that government regulations should not put anyone out of business. Instead, regulations should function in a way so as to improve an industries way of operating. The current FDA regulations in place have a set grandfather date on all premium cigars marketed in the United States as of February 15, 2007. This means that all premium cigars on the market in the U.S. prior to that date are exempt from FDA testing (protected). Every premium cigar on the market that was introduced after that date is now subject to FDA Substantial Equivalence testing. To establish a grandfather date such as this that goes back nearly 12 years seems completely unfair. This would be a dream come true for all large corporations that have been present in the U.S. market prior to that date. It would wipe us small family owned companies off the map, and they would gain immediate market share.

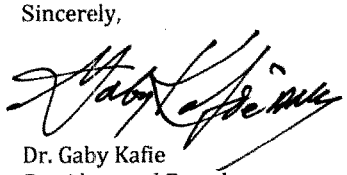
The member companies that are a part of our Association all have products that were introduced to the U.S. market after the February 15, 2007. This "grandfather date" protects the large corporations. It enables the corporations to control the market completely. Meanwhile, small business owners are tasked with an insurmountable expense. The repercussions will lead to the extinction of the family owned cigar company and the American dream. In a nutshell, the FDA will have created a monopoly. The premium cigar industry would be comprised of the top 5-7 corporations, and all family owned premium cigar companies would in essence be squeezed out of the marketplace.

It is for these reasons and many more, that our industry needs the protection of a premium cigar exemption. We as an Association believe that there should be strict standards implemented to preserve the definition of a premium cigar. Large premium cigars should be in a separate category than mass market machine made cigarillos. Our cigars are not sold in gas stations, convenience stores, or at local pharmacies behind the register. We firmly believe that there should be a clear and distinct definition of our products, and the connoisseurs we cater to. It's time to preserve a piece of history, not destroy it.

On behalf of the BCAA, I would like to thank you for taking the time to read our letter. Our Association is a proud supporter of Cigar Rights of America, as well as all family owned cigar companies in the United States. The future of our ability to earn a living doing what we have done for decades (some even over a century) is at stake. As a physician I took the Hippocratic Oath upon graduation. This oath, which I hold near and dear to my heart has an emphasis on "do no harm" as its mantra. I hereby declare to you and to all who are represented in this letter, if I felt we were doing any harm by making

premium cigars I would immediately stop. Our entire board of directors at the BCAA, as well as all our member companies thank you for your efforts. Please help our industry overcome this great obstacle that is before us.

Sincerely,



Dr. Gaby Kafie
President and Founder
kafietradingcompany@gmail.com

Dalton Healy
Vice President
daltonhealy408@gmail.com

Carter Skinner
Treasurer
carterskinner@gmail.com

Kerry Horney
Secretary
vstogie@gmail.com

Mike Palmer
Manager
mkepmr@gmail.com

Fouad Kashouty
Counselor
cigars@hiramandsolomoncigars.com

Joel Vazquez Marrero
Media Relations & Ambassador
joel@marrerocigars.com

CIGAR ASSOCIATION OF AMERICA, INC.

1310 G Street, NW
(Suite 680)
Washington, DC 20005

(202) 223-8204

www.cigarassociation.org

April 19, 2019

Chairman Marco Rubio
Senate Committee on Small Business and Entrepreneurship
428A Russell Senate Office Building
Washington, D.C., 20515

Re: Comments to be Made a Part of the Record of the April 5, 2019 Field Hearing of the U.S. Senate Committee on Small Business & Entrepreneurship

Dear Sir or Madam:

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

CAA has been, and continues to be, a strong advocate for the exemption of *all* premium cigars from FDA regulation. CAA submitted extensive comments to FDA's Advance Notice of Proposed Rulemaking on the "Regulation of Premium Cigars" in July 2018. Those comments not only outlined the factual reasons why premium cigars should be exempt from FDA regulation, but the comments also contained reports from three different experts on the scientific basis for why premium cigars should be exempt. Those comments, and the accompanying expert reports, are submitted with this statement.

CAA supports S. 9, introduced by Sen. Rubio, which seeks exemption of **all** premium cigars. This bill shows a thoughtful and deliberate understanding of the premium cigar industry and the cigars it produces. Premium cigars are handmade, artisanal products that at every stage -- from manufacturing, to distribution, to retail sale at Mom & Pop shops in every state support the livelihoods of tens of thousands of small businesses, and hundreds of thousands of jobs, across the country. FDA ignored the dramatic and unreasonably burdensome costs on this artisan industry when it imposed the draconian measures of the Deeming Rule on the premium cigar industry. CAA submitted comments detailing the defects of FDA's cost-benefit analysis in deeming cigars, including a comprehensive report and analysis by Policy Navigation Group of the costs FDA neglected to consider, to the FDA docket examining ways FDA could reform its regulations to be consistent with current administration policy. A copy of those comments and that report are also attached to this statement.

FDA claims that premium cigars are used by youth and young adults. The most recent available PATH data proves that youth usage of premium cigars in virtually non-existent. The facts are that youth usage of premium cigars (ages 12-17) is 0.02 percent.

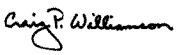
FDA claims that premium cigars are a pathway to tobacco initiation for youth. The PATH data proves this false because the median age of first regular use of premium cigars is 30.0 years old.

FDA claims that premium cigars are a gateway to use other tobacco products, most particularly cigarettes. Once again, the PATH data proves this false. Only 2.2% of premium cigar smokers ever progressed to everyday cigarette smoking during the duration of the PATH study, *at any age*.

FDA claims there is insufficient evidence that use patterns for premium cigars materially reduce health risks in comparison to other tobacco, most particularly cigarettes. Again, the most recent PATH data proves this false for three reasons. First, the prevalence of premium cigar usage is 0.53%. Second, 96.1% of premium cigar smokers smoke premium cigars less than daily. Third, the median monthly use of premium cigars is only 1.3 days per month, compared to 29.4 days per month for cigarette smokers.

The bottom line is that FDA's claims in support of the regulation of premium cigars – claims that FDA continues to make publicly – are not supported by facts or science.

Respectfully submitted,



Craig P. Williamson
President
Cigar Association of America, Inc.

Appendix 1

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

Dear Sir or Madam:

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

CAA submits the following in response to the request by the Food and Drug Administration ("FDA") for Comment on the Advanced Notice of Proposed Rulemaking ("ANPRM") entitled "Regulation of Premium Cigars."[1]

[1] Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018) ("Premium Cigar ANPRM").

Division of Dockets Management
Docket No. FDA-2017-N-6107 – Regulation of Premium Cigars
July 25, 2018

I. Introduction

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

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

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

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

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

[3] *Id.*

[4] 83 Fed. Reg. at 12,901.

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

II. Executive Summary

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

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

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

[7] Exhibit C, Report of Dr. Geoffrey Kabat (hereinafter the "Kabat Report").

[8] See attached Appendix A for a chart summarizing the areas of concentration of each expert report.

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

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

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

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[9] Final Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81. Fed. Reg. 28,974 at 29,020 (May 10, 2016) ("Final Rule").

[10] *Id.*

FDA Conventional Beliefs	The Facts
Youth Usage Premium cigars are used by youth and young adults.	***Youth usage of premium cigars is virtually non-existent.*** • Youth premium cigar prevalence (aged 12-17) decreased from 0.08% in Wave 1 and 0.04% in Wave 2 to 0.02% in Wave 3 (NERA). • Across all three waves prevalence among ages 12-14 was 0.00% (NERA).
Initiation and Progression Premium cigars are a pathway of tobacco initiation for youth.	***Premium cigars are not a pathway of initiation at an early age for use of other tobacco products.*** • Median age at first regular use of premium cigars is 24.8 years in Wave 1, 27.6 years in Wave 2, and 30.0 in Wave 3 (NERA). • Progression of premium cigar smokers to everyday cigarette smokers is statistically indistinquishable from non-smokers. (NERA)
Demographics Tobacco products are used by those that are young, less educated, and less economically affluent and evidence does not support that premium cigar users are differently situated.	***Premium cigars are used by those who are older, better educated, and more economically affluent non-minorities (based on Wave 3 NERA data).*** • 67% were 35 years or older (NERA) (and 89% of internet/mail-order retail purchases of premium cigars were made by adults of the same age group (EConsult)). • 52.7% of premium cigar smokers had completed college (NERA). • 44% of premium cigar smokers had a household income of $100,000 or more (NERA).
Usage Patterns and Frequency of Use The available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion.	***Premium cigar smokers are unlikely to also use cigarettes and for those cigarette smokers who use premium cigars they do so no more frequently than non-cigarette smokers.*** • Percentage of premium cigar smokers, of any age, that progress from never smoking cigarettes or smoking cigarettes some days in Wave 1 to everyday cigarette smoking in Wave 3 is about 2.2% (NERA). • Wave 3 premium cigar smokers who are also current cigarette smokers do not smoke more premium cigars than those who are not current cigarette smokers (NERA). ***Patterns of premium cigar use materially reduce health risks in comparison to other tobacco products.*** • Wave 3 prevalence of premium cigar usage is 0.53% (NERA). • Median monthly use of premium cigars in Wave 3 was 1.3 days per month and this compares to 29.4 days per month for cigarette smokers (NERA). • About 96.1% of premium cigar smokers smoke premium cigars less than daily (NERA).
Health Impacts Insufficient evidence that difference in use patterns for premium cigars substantially impact health analysis of premium cigar use.	***Difference in use patterns for premium cigars substantially impacts the health analysis of premium cigar use.*** • Cigar smokers (premium or otherwise) who smoke cigars less than daily (which includes 96.1% of premium cigar smokers) have no statistical difference in mortality rates as compared to non-smokers (Kabat). • Non-daily, exclusive smokers of cigars (of any kind) do not have an increased risk for smoking-related cancers, or an increased risk of death from all causes and certain specific causes (Kabat). • Non-daily premium cigar smokers have no increased health risks compared to non-smokers (Kabat).

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

III. Background of the Premium Cigar Industry

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

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

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

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

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

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

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

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

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

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

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

[15] Ex. B, Econsult Report at 8.

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

[17] *See* Ex. B, Econsult Report at 15-16, Figure 2 (demonstrating that purchasers of premium cigars exhibit little brand loyalty).

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

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

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

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

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

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

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

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

IV. Definition of Premium Cigar

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

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

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

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

[20] 83 Fed. Reg. at 12,903.

[21] Whenever the term "premium cigar" is used through this Comment, CAA uses this definition in reference to that term.

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

[23] 79 Fed. Reg. at 23,150.

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

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

- First, different retailers within a state apply state taxes differently. Specifically, some include it on the shelf (retail) price, while others add it with sales tax at checkout. The same cigar treated differently by retailers in a single state could end up being regulated differently.

- Second, state tax rates vary greatly from state to state and can result in a tax anywhere from zero to $3.50 per cigar. For this reason, the same cigar in different states could be regulated differently. Further, certain localities now impose taxes on premium cigars. For instance, in New York City, as of June 1, 2018, premium cigars have an additional NYC tax. Therefore, even within the same state, prices can differ simply based on taxes and how they are imposed.

- Third, a single cigar brand may be offered in several different sizes (length and ring gauge), most often seven to ten, with larger ones being more expensive. Premium cigars that use the same combination of wrapper, binder, and filler tobaccos, but differ in length, ring gauge and/or weight (and thus price) should not be regulated differently.

- Fourth, retail price is impacted by geography. The same cigar is more expensive in high cost cities than in low cost cities. The same cigar should not be regulated differently based solely on geography.

- Fifth, retail price is impacted by channel of distribution. The same cigar is often priced very differently when sold by a retail tobacconist than when sold through mail order or e-commerce, which generally have lower overhead costs. The same cigar should not be regulated differently based solely on channel of distribution.

- Sixth, retail price is largely beyond the control of the manufacturers. A cigar intended by the manufacturer to be premium could end up outside the category based on the price set by the retailer. The reverse is true as well.

- Seventh, retail price could be dependent on the manufacturing year. For instance, if there is a drought, the price of tobacco could increase requiring manufacturers to increase price, this ultimately would affect the retail price of the cigars. Additionally, if a certain tobacco is not available for a manufacturer to make more cigars one year, retailers may raise the price of that cigar due to the decreased supply of the cigar. Regulatory decisions should not be made based on retail price, which is not always a stable, set price for any particular cigar year to year.

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

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

> [a]ffording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period of the tobacco. It also will allow the users to capture the aroma of the cigar and the box (if the cigar is sold in a package).
>
> ....
>
> The same warning statement requirements will apply to cigars sold individually and not in product packages. However, instead of being required to place warnings directly on these product packages, retailers will be required to post signage at the point of sale....[24]

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

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[24] 81. Fed. Reg. 28,974 at 29,026, 29,061.

[25] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res., ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423 (finding that 79% of in person premium cigar purchases were of single cigars).

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

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

FDA has asked if "action[s] directed to consumers, by a retailer or manufacturer, such as through labeling, advertising, or marketing, which would reasonably be expected to result in consumers believing that the tobacco product is a premium cigar", should be included in the definition of premium cigar.[26] CAA believes they should not. If a cigar meets the definitional requirements outlined above, CAA does not view otherwise permissible labeling, advertising, or marketing actions to be an appropriate or objective benchmark to include in the definition of premium cigar. Additionally, while manufacturers can control all advertising and marketing they create for their products, similar to retail price, they do not control the advertising that individual retailers or distributors may do for their products. It would be inappropriate, therefore, to incorporate into any definition of premium cigar a component that the manufacturers cannot fully control.

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

[26] 83 Fed. Reg. at 12,903.

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

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

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

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

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

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

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

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

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

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

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

[30] Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018).

[31] 83 Fed. Reg. at 12,903.

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

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

[32] 81 Fed. Reg. at 29,026.

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

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

[33] 83 Fed. Reg. at 12,903.

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

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

V. Use Patterns of Premium Cigars

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

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

[36] *Id.* This is yet another reason why "size" of the cigar should not be a component of the definition of premium cigars.

[37] *Id.*

[38] 81 Fed. Reg. at 29,020.

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

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

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

[39] *See* Ex. A, The NERA Report; Ex. B, Econsult Report; Ex. C, Kabat Report.

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

[41] *See* Ex. A, NERA Report at ¶¶ 4, 7.

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

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

[43] Corey C, et al. *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*; Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

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

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

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

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

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

[47] Supplement to: Kasza KA, Ambrose BK, Conway KP, et al., *Tobacco-product use by adults and youths in the United States in 2013 and 2014*, N. Eng. J. Med. 376, 342-53 (2017). DOI: 10.1056/NEJMsa1607538; Table S18.

[48] *Id.* at Table S4.

[49] 81 Fed. Reg. 29,020.

[50] Ex. A, NERA Report at ¶¶ 25, 26, Table 1.

[51] *Id.*

[52] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423

[53] Ex. A, NERA Report at ¶28, Table 2.

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

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

[54] *Id.*

[55] Ex. B, Econsult Report at 9, Table 4.

[56] Ex. A, NERA Report at ¶¶ 37, 38, Table 3c.

[57] Ex. B, Econsult Report at 19-21, Table 14, Figures 4, 5.

[58] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014,* Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

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

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

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

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[59] *Id.*

[60] Ex. A, NERA Report at ¶49, Table 5c.

[61] *Id.* at ¶¶ 47, 49, Tables 5a and 5c.

[62] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014,* Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

[63] Ex. B, Econsult Report, at 15-16, Figure 2.

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

Fourth, Corey et al. reported that the median price paid was $7.49 per premium cigar. In contrast, the median price was $1.00 for non-premium cigars and cigarillos.[69]

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

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[64] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

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

[66] Ex. B, Econsult Report at 8.

[67] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423

[68] *Id.*

[69] *Id.*

[70] *Id.* at Table 3.

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

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

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

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[71] *Id.* It should be noted that there is a federal prohibition on the sale of single cigarettes.

[72] Ex. B, Econsult Report at 15, Table 12.

[73] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

[74] Ex, A, NERA Report at ¶44, Table 4c.

[75] Ex. B, Econsult Report at 12, Table 7.

[76] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017), Supplementary Table B available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

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

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

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

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

[78] *Id.*

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

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

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

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

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

[81] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423

[82] Ex. A., NERA Report at ¶59, Table 9c.

[83] *Id.* at ¶7(iv)

[84] *Id.* at Table 10c.

[85] *Id.* at ¶51, Table 6.

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

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

VI. Public Health Considerations Associated with Premium Cigars

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

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

[86] *Id.* at ¶51 (emphasis added).

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

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

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

[88] Ex. A, NERA Report at Table 1.

[89] *Id.* at ¶49, Table 5c.

[90] *Id.*

[91] Ex. A, NERA Report at ¶37, Table 3.

[92] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423.

[93] Ex. A, NERA Report at ¶44, Table 4c.

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

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

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[94]Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017 https://www.ncbi.nlm.nih.gov/pubmed/29059423 at Table 2.

[95] *Id.*

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

[97] Ex. A, NERA Report at ¶44, Table 4c.

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

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

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

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

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

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

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

[99] *See*, Ex. C, Kabat Report.

[100] Ex. C, Kabat Report at 6.

[101] *Id.* at 7.

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

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

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

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

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

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

[102] 81 Fed. Reg. at 29,020.

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

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

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

[103] Tobacco Control Act § 904.

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

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

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

[104] 81 Fed. Reg. at 29,052(emphasis added).

[105] Tobacco Control Act § 915(a).

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

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

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

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

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

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

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

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

[108] *See* Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (November 2017).

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

[110] Tobacco Control Act § 910((a)(2)(B).

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

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

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

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[112] Dr. Matt Holman, "TMA 2018 Annual Meeting," slide 16, April 11, 2018. CAA understands Dr. Holman's presentation was not an official statement by FDA, but uses this information simply as guidance and background for preparation of the positions outlined in this Comment.

[113] *Id.* at slide 17.

[114] *See* Tobacco Control Act § 3(4). *See also e.g.* Tobacco Control Act §§ 906, 907, 909, 102.

[115] Ex. B, Econsult Report, at 8, Table 3.

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

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

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

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

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

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

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

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

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

> [c]hanges in product quantity can affect initiation and cessation, such as by affecting consumer harm perceptions, use intentions and use behavior. The information in these Product Quantity Change SE Applications would allow for FDA to fully evaluate the potential of such changes in product quantity to determine whether the new product raises different questions of public health....[117]

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

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

[117] *Id.* at 7.

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

[119] *See* Section V, above.

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

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

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

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

[121] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) available at https://www.ncbi.nlm.nih.gov/pubmed/29059423

[122] Ex. A, NERA Report at ¶44, Table 4c.

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

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

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

[123] Ex. B, Econsult Report at 14-15, Tables, 9-12.

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

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

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

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

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

[125] 80 Fed. Reg. at 57,532

[126] *Id.*

[127] *Id.*

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

C. The Health Warning Requirements are Unjustifiable

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

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

[128] 21 C.F.R. §1143.5.

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

> Finally, both the balance of equities and the public interest favor an injunction pending appeal.
>
> In the end, this court believes that Plaintiffs are entitled to a full hearing before an appellate court without the specter of a warnings regime going into effect that might ultimately be found to run afoul of the First Amendment. [130]

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

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

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

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

[131] 81 Fed. Reg. at 29,026, 29061; Final Regulatory Impact Analysis at 62.

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

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

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

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

[133] This is similar to the system in place in the European Union for cigars. The regulation in the European Union outlines that if "the health warnings referred in 1 & 2 are to appear on a surface exceeding 150 cm2, the warnings shall cover an area of 45 cm2." Directive 2014/40/EU, Art. 11(4).

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

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

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

VIII. Premium Cigars Should be Exempt from Regulation

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

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

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

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

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

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

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

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

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

[137] Executive Order 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

[138] Executive Order 13,777, 82 Fed. Reg. 12,285, sec. 1. (Feb. 24, 2017).

[139] 81 Fed. Reg. 29,020.

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

IX. Conclusion

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

Respectfully Submitted,

Craig Williamson
President
Cigar Association of America, Inc.

[140] Ex. B, Econsult Report at 8.

Division of Dockets Management
Docket No. FDA-2017-N-6107 – Regulation of Premium Cigars
July 25, 2018

Appendix A

Expert Report	Topic	Major Findings
NERA Economic Consulting	Prevalence of cigar usage	• Prevalence of youth cigar usage • Prevalence of adult cigar usage • Demographic characteristics of cigar and cigarette users, Wave 1-Wave 3 of the PATH Study
	Frequency and intensity of premium cigar use	• Prevalence of smoking • Days smoked in past 30 days • Number of sticks per day in days smoked • Number of sticks smoked per day in past 30 days
	Initiation of use and progression to use other tobacco products	• Age at initiation • Progression from cigar smoking to cigarette smoking • Current cigar smokers transition to cigarette smoking
	Dual usage of premium cigars and cigarettes	• Cigarette smoking status – current, former, never • Prevalence of now smoke cigarettes every day • Number of cigarette smoking days in past 30 days • Number of cigarettes per day on days smoked • Number of cigarettes per day in past 30 days
EConsult Solutions	Market size and share	• Share of cigar market defined by Catherine Corey • Percent of premium cigar market defined by Corey
	Total premium cigar transactions	• Summary statistics of total premium cigar transactions – orders, unique customers, cigars sold, SKUs, cigar revenue
	Customer age	• Stratified age cohorts of online premium cigar purchasers • Comparison of premium cigar purchasers to overall US population by cohort
	Purchasing patterns	• Unique customers, orders, unique SKUs sold, number of cigars sold, total revenue, price per cigar, average spend • Cigar units and expenditures by month • Frequency of repeat purchasing over a four-year period • Average cigars per order and average spending per order • Order characteristics
	Demographics	• Percent of urban population purchasing premium cigars • Median household income of the census tract of premium cigar purchasers • Education level of premium cigar purchasers compared to US population
Dr. Geoffrey Kabat	Epidemiology	• Review of three studies examining prevalence data on the use of premium cigars – youth usage, age of initiation, frequency of smoking, number of days smoked in past 30 days • Review of three mortality studies plus a pooled analysis of five cohort studies 'examining the association of cigar use with health outcomes • Review of one study and one abstract which examined biomarkers of tobacco smoke exposure among cigar smokers

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

EXHIBIT A

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

REPORT REGARDING CONSUMPTION PATTERNS OF PREMIUM CIGARS

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

July 25, 2018

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I. INTRODUCTION

A. Assignment

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

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

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

[1] Federal Register, Vol. 83, No. 58, p.12902. Monday, March 26, 2018 Proposed Rules.

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

B. Population Assessment of Tobacco and Health Study

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

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

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

[3] PATH Restricted-Use Data User Guide, p. 2.

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

C. Summary of Opinions

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

i. The prevalence of premium cigar usage and the demographic characteristics of premium cigar consumers differ from that of non-premium cigar products and cigarette users. For example, in Waves 1, 2 and 3, among youth, the prevalence of non-premium cigar use is 16.5 to 25 times that of premium cigars. Similarly, among adults, the prevalence of non-premium cigar use is more than 3.7 to 4.5 times that of premium cigars. Prevalence is the estimated weighted percentage of respondents who are identified as current cigar or cigarette users.

a. Among the 11,814 respondents aged 12 to 17 in the recently released Wave 3, there is only one current premium cigar user, or a 0.02% prevalence. In Wave 3, the premium cigar prevalence for respondents aged 12 to 17 remains lower than that of any single non-premium cigar—in the 0.05% to 0.35% range—and cigarettes with a 1.77% rate. No respondents aged 12-14 reported using premium cigars. Similar results are obtained for the first and second waves of data collection. The prevalence of premium

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

[5] PATH Restricted-Use Data User Guide, p. 8.

[6] PATH Restricted-Use Data User Guide, p. 18.

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

b. Among adults, the prevalence of premium cigar use is statistically significantly less than that of non-premium cigars and cigarettes across all three waves of PATH data. Overall, in Wave 1, the prevalence of premium cigar use is 0.56% as compared to 2.51% for non-premium cigars. In Wave 2, the prevalence of premium cigar use increased slightly to 0.58%, but remains statistically significantly less than the 2.16% for non-premium cigars. In Wave 3, the prevalence of premium cigar use drops to 0.53%, and again, is statistically significantly less than the 1.94% for non-premium cigars. As compared to the detailed non-premium cigar types, the prevalence of premium cigars is statistically significantly less than cigarillos and filtered cigars in all three Waves, and statistically significantly less than non-premium traditional cigars in Wave 1. See Table 2.

c. Premium cigar users are typically white males, 35 years or older, who have higher levels of education and higher incomes than consumers of non-premium cigar or cigarettes. In Wave 3, 81% of adult premium cigar users were white, 98% were male, and 67% were 35 years or older. In addition, 83% of premium cigar users aged 25 and up have higher-level education, and 53% completed college. In comparison, 17% of non-premium cigar users, 11% of cigarillo smokers, 5% of filtered cigar smokers, and 12% of cigarette smokers age 25 and older completed college. Finally, 44% of premium cigar users have a household income of $100,000 or more, as compared to 13% of non-premium traditional cigars, 10% of cigarillo, 4% of filtered cigar, and 8% of cigarette smokers. Similar results are obtained for the first and second waves of data collection. See Table 3a, Table 3b, and Table 3c.

ii. Among adult current users, premium cigar consumers were less likely to use them daily, used them on fewer days and consumed fewer cigars per day than users of non-premium cigar or cigarette users. In Wave 3, the most current PATH data, about 3.9% of premium cigar consumers smoked them daily. Premium cigar users typically used them 1.3 days out of 30, as reported by the median and smoked 0.1 cigars per day in past 30 days. In comparison, 20.7% to 40.9% of non-premium cigar consumers smoked them every day, used them on 4.4 to 14.5 days out of 30 and smoked 0.2 to 0.9 non-premium cigars per day in past 30 days. For cigarette smokers, 77.0% smoked cigarettes every day. The median cigarette smoker smoked on 29.4 of the past 30 days, and smoked 9.9 cigarettes per day in past 30 days. Similar results are obtained for the first and second waves of data collection. See Table 4a, Table 4b, and Table 4c.

iii. Most cigarette smokers experiment and progress to becoming established smokers between the ages of 12 and 24.[7] Using the most recent PATH data, we find that the median age at first regular use is 30.0 years for premium cigar users, older than that of cigarillo and cigarette users. We also find that premium cigar users are as likely to become cigarette users as those who do not use any tobacco product and are less likely than users of non-premium cigar.

   a. In Wave 1, the median age at first regular use reported by premium cigar users is 24.8 years. In comparison, the median age at first regular use is 19.4 years for non-premium traditional cigars, 18.0 years for cigarillo users and 16.6 years for cigarette users. Filtered cigar users, like premium cigar users, were generally older at initiation, with a median age at first regular use of 26.8 years. In Wave 3, the median age at first regular use increased to 30.0 years for premium cigar users. The median age at first regular use for non-premium cigar ranged from 24.2 years for cigarillos to

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

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

b. The percentage of premium cigar users that progress from never smoking cigarettes or smoking cigarettes some days in Wave 1 to everyday cigarette smoking in Wave 3 is 2.2%. In comparison, 9.1% of non-premium traditional cigar users, 11.5% of cigarillo users, 26.4% of filtered cigar users and 1.1% of not tobacco users transition to smoking cigarettes everyday by Wave 3. The difference between the 2.2% transition rate for premium cigar users and the 1.1% for respondents that did not use tobacco products is not statistically significant. Similar results are obtained for transition into some day cigarette smoking. See Table 6 and Table 7.

c. Of adults who are current established premium cigar users and are also current established cigarette users, 78.8% smoked cigarettes first before they started smoking traditional cigars—premium or not-premium, 10.1% started smoking traditional cigars before they started to smoke cigarettes and 11.0% started smoking traditional cigars and cigarettes at the same age. See Table 8.

iv. The prevalence and intensity of dual usage of cigars and cigarettes is less for premium cigar users than for non-premium cigar users.

a. In Wave 3, for current premium cigar users, the median number of cigarette smoking days and the number of cigarettes smoked per day in past 30 days are zero (0). In comparison, the non-premium traditional cigar user typically smoked cigarettes on 1.6 days in past 30 days and smoked 0.1 cigarettes per day in past 30 days. The cigarillo smoker typically smoked cigarettes on 8.0 days in past 30 days and smoked 1.0 cigarettes per day in past 30 days. The filtered cigar smoker typically smoked cigarettes on 28.3 days in past 30 days and smoked 5.9 cigarettes per day in past 30 days. See Table 9c.

b. Also in Wave 3, non-premium traditional cigar users were more than twice as likely to smoke cigarettes when compared to premium cigar users. These differences increase when compared to cigarillos and filtered cigars. For example, in Wave 3, 23.8% of premium cigar users also smoked cigarettes as compared to 51.3% of non-premium traditional cigar users, 56.3% of cigarillo users and 69.8% of filtered cigar users. Similar results are obtained for the first and second waves of data collection. See Table 9a, Table 9b, and Table 9c.

c. Among current premium cigar users in Wave 3, those who are also current cigarette users do not use more premium cigars. They use premium cigars 0.7 days per month as compared to 1.5 days per month for those who are not current cigarette smokers. Premium cigars smoked, per day in past 30 days, among these two groups, is less than 0.1 cigars per day for current cigarette smokers and also for those who are not current cigarette smokers. Similar results are obtained for the first and second waves of data collection. See Table 10a, Table 10b, and Table 10c.

D. Qualifications

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

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

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

II. PATH DATA AND IDENTIFICATION OF PREMIUM CIGARS

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

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

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

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

used the terms "Cigar" or "Cigars" in combination with the terms "PATH" or "NATS" or "NYTS" to identify potentially relevant articles.[10] Appendix A provides a summary of the process used to identify and select relevant academic studies of tobacco usage. We identified only one study - "U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014" by Corey et al.– that analyzed tobacco use in the U.S. by cigar type and distinguished between premium and non-premium traditional cigars.[11]

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

12. In 2017, Corey et al. published the results of their analysis of "U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014" (the "Corey Study") and noted that "despite the diversity in the cigar market place," most tobacco studies treated cigars as a single product type. In their study, they distinguished between traditional cigars, cigarillos and filtered cigars, and further divided traditional cigars into premium and non-premium. They found that user characteristics, cigar smoking patterns and dual smoking with cigarettes varied by cigar type, and that sufficient descriptions of cigar types, as well as distinguishing between premium and non-premium traditional cigars, is important to "enhance tobacco regulatory science."

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

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

[11] Corey, C. G., Holder-Hayes, E., Nguyen, A. B., et al. (2017), "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014", *Nicotine & Tobacco Research.*

Prevalence is the estimated weighted percentage of adult respondents who are identified as adults who are current cigar or cigarette smokers.[12]

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

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

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

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

[13] Federal Register, Vol. 83, No. 58, March 26, 2018. Proposed Rules, p. 12902.

[14] Federal Register, Vol. 83, No. 58, March 26, 2018. Proposed Rules, p. 12903.

B. Identification of Premium Cigars

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

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

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

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

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

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

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

[17] Corey et al. (2017), p. 8.

Restricted Use data set that were identified by respondents in Wave 2 and 3, but were not in Wave 1.[18]

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

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

III. PREVALENCE AND USE PATTERNS OF CIGAR USAGE

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

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

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

A. Prevalence of Cigar Usage

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

1. Prevalence of Youth Cigar Usage[20]

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

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

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

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

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

Notes and Sources:

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

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

[2] Prevalence is the estimated weighted percentage of youth respondents who are identified as current users of cigars or cigarettes.

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

2. Prevalence of Adult Cigar Usage[22]

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

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

[22] Prevalence is the estimated weighted percentage of adult respondents who are identified as adults who are current cigar or cigarette smokers.

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

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

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

Notes and Sources:

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

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

[2] Prevalence is the estimated weighted percentage of adult respondents who are identified as current users of cigars or cigarettes.

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

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

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

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

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

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

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

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

Notes and Sources:

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

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

[2] Household poverty is from field "3 level poverty status based on annual household income and HHS poverty guidelines." Th field is only available in Wave 1, not Wave 2 or Wave 3.

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

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

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

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

	Premium Cigars		Non-Premium Cigars			
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	Cigarettes
	(1)	(2)	(3)	(4)	(5)	(6)
Age group (%)						
18-24	12.4%	11.4%	15.5%	27.5%	15.5%	12.5%
25-34	25.7	25.1	23.5	28.1	20.1	23.6
35-54	35.1	35.4	36.1	31.1	35.9	39.1
55+	26.8	28.1	25.0	13.3	28.4	24.7
Sex (%)						
Male	97.5%	97.7%	85.1%	75.0%	64.2%	54.8%
Female	2.5	2.3	14.9	25.0	35.8	45.2
Race/ethnicity (%)						
White, non-Hispanic	84.5%	84.1%	58.8%	47.4%	61.8%	68.4%
Black/AA, non-Hispanic	4.5	4.3	24.4	32.5	19.4	13.7
Other or multi-race, non-Hispanic	3.9	4.0	3.8	5.8	4.6	5.9
Hispanic	7.2	7.7	13.0	14.3	14.2	12.0
Education for adults aged 18+ (%)						
Less than high school diploma	3.5%	3.8%	15.7%	17.1%	21.3%	16.5%
GED	4.1	4.4	15.0	10.6	9.1	11.3
High school diploma	14.2	11.3	22.8	24.4	27.9	27.5
Some college/associate degree	33.0	33.5	34.4	38.0	33.7	33.2
Completed college or more	45.2	46.9	12.1	9.9	8.1	11.5
Education for adults aged 25+ (%)						
Less than high school diploma	3.1%	3.4%	15.1%	17.2%	22.2%	16.6%
GED	4.1	4.4	14.6	10.9	9.6	11.3
High school diploma	12.2	9.1	22.1	22.5	28.3	27.1
Some college/associate degree	31.4	32.3	34.4	37.8	31.2	32.6
Completed college or more	49.1	50.8	13.9	11.7	8.8	12.3
Household income (%)						
Less than $10,000	4.4%	4.5%	27.5%	29.6%	39.6%	21.5%
$10,000-$24,999	9.3	7.6	25.5	27.0	28.3	27.4
$25,000-$49,999	18.8	18.1	22.0	17.5	17.4	24.2
$50,000-$99,999	32.0	32.1	14.2	17.2	10.8	19.4
$100,000-$199,999	25.4	27.0	9.8	7.1	2.8	6.3
$200,000 or more	10.2	10.8	1.0	1.5	1.0	1.2
Number of users	270	248	243	790	473	9,694

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

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

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

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

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

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

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

Notes and Sources:

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

B. Frequency and Intensity of Premium Cigar Use

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

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

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

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

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

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

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

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

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

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

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

1. Age at Initiation

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

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

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

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

Notes and Sources:

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

[1] Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

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

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

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

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

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

Notes and Sources:

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

[1] Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

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

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

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

Notes and Sources:

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

[1] Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

2. Progression to Everyday Cigarette Smoking

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

a. Current Cigar Smokers Transition to Regular Cigarette Smoking

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

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

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

	Current Users of					
	Premium Cigars		Non-Premium Cigars			Not Current
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	Tobacco Users
	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Respondents					
Not Everyday Cigarette Users as of Wave 1	173	161	170	469	148	12,584
Progress to Everyday Cigarette Users in Wave 3	5	5	20	56	38	302
Remain as Not Everyday Cigarette Users in Wave 3	168	156	150	413	110	12,282
	Weighted Percentage					
Not Everyday Cigarette Users as of Wave 1	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Progress to Everyday Cigarette Users in Wave 3						
Percentage	2.2%	2.3%	9.1%	11.5%	26.4%	1.1%
Confidence Interval	(0.1-4.3%)	(0.1-4.6%)	(5.6-12.6%)	(8.3-14.8%)	(19.0-33.7%)	(1.0-1.3%)
Remain as Not Everyday Cigarette Users in Wave 3						
Percentage	97.8%	97.7%	90.9%	88.5%	73.6%	98.9%
Confidence Interval	(95.7-99.9%)	(95.4-99.9%)	(87.4-94.4%)	(85.2-91.7%)	(66.3-81.0%)	(98.7-99.0%)

Notes and Sources:

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

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

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

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

	Current Users of					
	Premium Cigars		Non-Premium Cigars			Not Current
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	Tobacco Users
	(1)	(2)	(3)	(4)	(5)	(6)
Number of Respondents						
Not Someday Cigarette Users as of Wave 1	149	138	101	252	77	11,993
Progress to Someday Cigarette Users in Wave 3	9	9	15	48	20	596
Remain as Not Someday Cigarette Users in Wave 3	140	129	86	204	57	11,397
Weighted Percentage						
Not Someday Cigarette Users as of Wave 1	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Progress to Someday Cigarette Users in Wave 3						
Percentage	5.9%	6.4%	13.2%	17.3%	29.5%	2.5%
Confidence Interval	(1.7-10.0%)	(1.8-10.9%)	(5.8-20.6%)	(13.1-21.4%)	(19.3-39.7%)	(2.2-2.8%)
Remain as Not Someday Cigarette Users in Wave 3						
Percentage	94.1%	93.6%	86.8%	82.7%	70.5%	97.5%
Confidence Interval	(90.0-98.3%)	(89.1-98.2%)	(79.4-94.2%)	(78.6-86.9%)	(60.3-80.7%)	(97.2-97.8%)

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

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

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

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

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

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

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

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

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

D. Dual Use of Premium Cigars and Other Tobacco Products

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

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

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

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

Notes and Sources:

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

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

[2] Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

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

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

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

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

Notes and Sources:

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

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

[2] Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

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

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

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

Notes and Sources:

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

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

[2] Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

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

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

IV. MISCELLANEOUS

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

July 25, 2018

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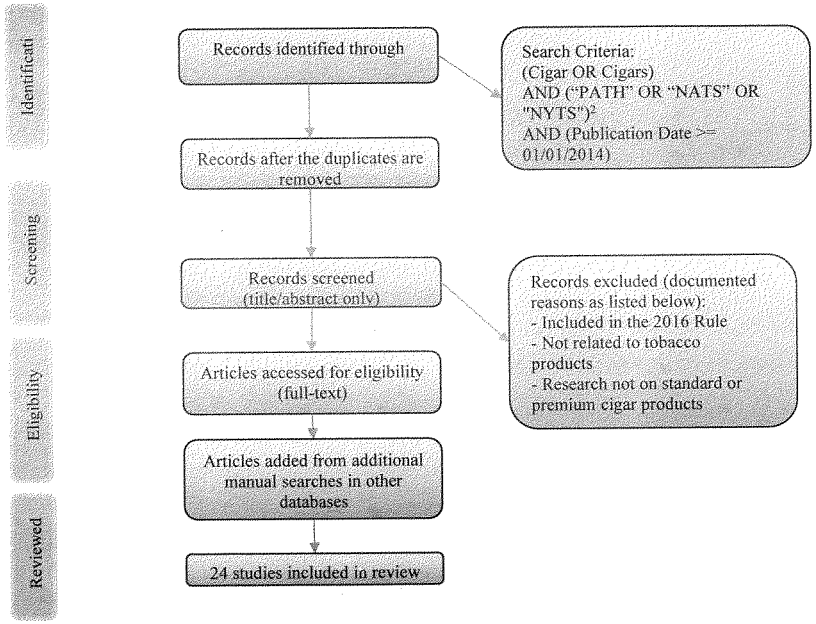
APPENDIX A

Table 11. *Literature Review*

Process of Selecting Relevant Academic Studies



Notes and Sources:
[1] The databases searched are: PubMed, ISI Web of Science, and Embase.
[2] PATH: Population Assessment of Tobacco and Health; NATS: National Adult Tobacco Survey; NYTS: National Youth Tobacco Survey.

Summary of Recent Studies on Traditional Cigar Smoking Patterns

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

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

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

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

15.	Pierce, et al. (2018)	Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study	Cigars (including traditional cigars, cigarillos, and filtered cigars), electronic cigarettes, cigarettes, and smokeless tobacco products	PATH	10,989 respondents aged 12-24 who had no tobacco product use in Wave 1	Initiation/Progression; Labelling/Advertising	Receptivity to tobacco product advertising is substantial among US youth who are below the minimum required age to purchase tobacco products. Among young committed never users, receptivity is significantly associated with progression toward use within a 1-year period. In general, receptivity to cigar ads is lowest for all age groups, whereas receptivity to e-cigarette ads is highest.
16.	Protano, et al. (2017)	Second-hand Smoke Generated by Combustion and Electronic Smoking Devices Used in Real Scenarios: Ultrafine Particle Pollution and Age-Related Dose Assessment	Combustion (conventional and hand-rolled cigarettes, a cigar and tobacco pipe) and non-combustion (e-cigarette and IQOS®) devices	N/A	4 volunteer smokers (three male and one female of 60, 58, 53, and 37 years old), all of whom were employees of the Sapienza University of Rome	Characterization of smoke dispersal and second-hand smoke transmission	Aerosol measurements were carried out in a model room where both combustion and non-combustion devices were smoked. Regardless of the smoking device, the highest doses were received by infants, which reached 9.88×108 particles/kg bw during a cigar smoking session. Moreover, 60% to 80% of the particles deposited in the head region of a 3-month-old infant were smaller than 100nm and could be translocated to the brain via the olfactory bulb. The doses due to second-hand smoke from electronic devices were significantly lower, below 1.60×108 particles/kg bw, than those due to combustion devices. Dosimetry estimates were 50% to 110% higher for IQOS® than for e-cigarettes.
17.	Roberts, et al. (2017)	Rural versus Urban Use of Traditional and Emerging Tobacco Products in the United States, 2013-2014	Cigars, cigarillos, pipes, smokeless tobacco, e-cigarettes, cigarettes, and hookah	PATH	32,320 adults (18+)	Dual Use; Difference between Urban and Rural populations	No non-rural difference in the use of cigars, although the daily use of cigarettes and smokeless tobacco were higher in Rural populations, and the use of Cigarillos and Hookah were higher in Urban than Rural populations, at the P < .001 level.
18.	Rostron, et al. (2016)	Dependence Symptoms and Cessation Intentions among US Adult Daily Cigarette, Cigar, and E-cigarette Users, 2012-2013	Cigarettes, cigars (including large cigars, cigarillos, and little filtered cigars), and e-cigarettes	NATS	5,617 daily tobacco users that used a combination of cigars, cigarettes, and e-cigarettes (who either reported using a single product type every day or being a multi-product user and using at least one tobacco product every day)	Dual Use; Frequency of Use; Dependence	1) Among daily tobacco users, dual cigarette and cigar users show evidence of greater dependence symptoms -- they smoked more cigarettes per day (17.3 vs. 15.8), had shorter times to first tobacco use after waking (21.4 min vs. 25.9 min), and were more likely to report dependence symptoms (withdrawal and craving) than exclusive cigarette smokers. 2) Dual cigarette and e-cigarette users were more likely than exclusive cigarette smokers to report withdrawal and craving symptoms and cessation intentions. 3) Exclusive cigar and e-cigarette users were less likely to report dependence symptoms than users of other products, but more than a third of exclusive cigar users reported strong cravings for tobacco in the past 30 days.

19.	Singh, et al. (2016)	Tobacco Use Among Middle and High School Students--United States, 2011-2015	Cigarettes, cigars, smokeless tobacco, electronic cigarettes , hookahs, pipe tobacco, and bidis	NYTS	U.S. students in grades 6-12. Sample sizes and overall response rates were 2011: 18,866 (72.7%); 2012: 24,658 (73.6%); 2013: 18,406 (67.8%); 2014: 22,007 (73.3%); and 2015: 17,711 (63.4%)	Prevalence, Frequency of Use	In 2015, e-cigarettes were the most commonly used tobacco product among middle (5.3%) and high (16.0%) school students. During 2011-2015, current use of e-cigarettes and hookahs significantly increased for both middle school and high school students, whereas current use of conventional tobacco products, such as cigarettes and cigars decreased. During 2014-2015, current use of e-cigarettes increased among middle school students, whereas current use of hookahs decreased among high school students; in contrast, no change was observed in use of hookahs among middle school students, use of e-cigarettes among high school students, or use of cigarettes, cigars, smokeless tobacco, pipe tobacco, or bidis among middle and high school students. In 2015, an estimated 4.7 million middle and high school students were current tobacco product users.
20.	Soneji, et al. (2017)	Engagement with Online Tobacco Marketing and Associations with Tobacco Product Use among U.S. Youth	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, snus ouches, dissolvable tobacco, bidis, kreteks, and smokeless tobacco	PATH	13,651 youths aged 12-17 years old	Initiation/Progression: Labelling/Advertising	12% of youth engaged in one or more forms of online tobacco marketing. Compared to no engagement, the odds of susceptibility to the use of any tobacco product among never-tobacco users was independently associated with the level of online engagement. Similarly, higher levels of receptivity to tobacco marketing in traditional media venues were also associated with these tobacco-related outcomes, independent of on-line engagement. The prevalence of susceptibility was lower for cigars than for cigarettes, and e-cigarettes despite the level of online engagement for both ever smokers and smokers that have used tobacco for the past 30 days. For example, for those who have ever smoked tobacco, the prevalence of susceptibility for cigars ranged from 6.7 (no tobacco product online engagement) to 26.0 (two or more types of tobacco product online engagement) as compared to 12.5 to 39.2 for cigarettes.
21.	Strong, et al. (2017)	Indicators of Dependence for Different Types of Tobacco Product Users: Descriptive Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study	Cigars (including traditional cigars, filtered cigars, and cigarillos), cigarettes, e-cigarettes, hookah, and smokeless tobacco products	PATH	14,287 current established users of tobacco products	Nicotine Dependence	The PATH study questionnaire included 24 tobacco dependence ("TD") symptoms derived from four primary instruments used to represent multiple domains of TD. With levels of TD anchored at 0 (SD=1.0) for cigarette only users, the mean TD were more than a full standard deviation lower for cigar only users (mean= -1.92, SD=2.11). The lowest levels of TD relative to cigarette smokers were seen in e-cigarette users only, cigar only users (lowest, TD=-1.92), and hookah only users.
22.	Strong, et al. (2018)	Marijuana Use among US Tobacco Users: Findings from Wave 1 of the Population Assessment of Tobacco Health (PATH) Study	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, and smokeless tobacco	PATH	32,212 respondents from Wave 1 of the PATH Study	Correlation between tobacco use and marijuana use	1) When compared to non-current tobacco users, each tobacco user group except smokeless only users had higher odds of reporting current marijuana use. 2) Among current tobacco users, higher levels of tobacco dependence did not explain the relationship between tobacco use and marijuana use. 3) Concurrent marijuana use was associated with lower odds of attempts to quit tobacco (OR=0.86, 95% CI=0.79, 0.94, $p < 0.001$) and a higher probability (OR=1.35, 95%CI=1.21, 1.51, $p < 0.01$) of reporting a history of respiratory disease. 4) Marijuana use may represent an additive risk for respiratory harm among concurrent users of tobacco and marijuana. In terms of cigars, current cigar-only users had significantly higher odds of reporting current marijuana use than all other types of tobacco analyzed, but lower than the multiple product users.

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

Notes and Sources:

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

APPENDIX B

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

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

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

Notes and Sources:

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

[1] Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

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

EXHIBIT B

PURCHASING PATTERNS AND DEMOGRAPHICS OF ONLINE PREMIUM CIGAR CUSTOMERS

Expert Report Prepared For:

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

Prepared By:

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

July 25, 2018

1.0 Econsult Solutions, Inc.

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

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

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

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

2.0 Scope of Work

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

Data on the purchasing and use patterns of premium cigars has, up until now, been very limited. The dearth of information is in part a result of the fact that premium cigars are not defined as a class by the federal government, and are not routinely included in survey data or more general consumption data. Moreover, premium cigars are not sold in traditional mass-market channels. This stands in contrast to other types of cigars and cigarettes, where data is available from usage surveys and from scanner data as these products are sold in retail channels that are easily traceable. In order to examine purchasing patterns, therefore, it is necessary to conduct surveys of premium cigar consumers or to collect data from individual premium cigar retailers. To date, this has not been done using a verifiable analytical methodology. This analysis has taken data from five of the largest internet/mail-order retailers of premium cigars in order to analyze purchasing patterns of premium cigar consumers, and provides a new,

much more comprehensive window on the purchasing, and by implication, use patterns of premium cigars.

3.0 Executive Summary

Using a definition of "premium" cigar developed by a researcher at FDA's Center for Tobacco Products (CTP), this report analyzes sales data for approximately 125 million premium cigars in 2017. The data provided by the companies allows for analysis of premium cigar purchasing patterns that has never before been undertaken.

The data from these companies provide important demographic information about premium cigar purchasers. For example, it shows the average premium cigar purchaser is 55 years old, with a median age of 57, and that 89% of these consumers are over age 35. Further, premium cigar purchasers reside in communities with higher levels of education and higher incomes than the rest of the US population, and reside predominantly in urban environments. In addition, the data show no youth purchases, because all of these companies use third party age-verification to ensure that all consumers are of at least legal minimum age of purchase.

The data also shed light on the distinct purchasing patterns of premium cigar consumers. For the most part, these consumers purchase infrequently, and approximately 44% of the purchasers in this dataset made only a single purchase, and only 17% of premium cigar consumers average more than 2 purchases per year. In addition, premium cigar consumers do not display great brand loyalty, preferring instead to purchase a variety of brands. This differs from what is typically assumed of consumers of tobacco products. Additionally, and unlike purchases of other tobacco products, premium cigar purchases are not spread evenly throughout the year; rather they peak before the December holidays, around Father's Day, and in the summer.

Regarding how premium cigars are sold, the data shows that in 2017, these retailers on average had approximately 10,000 individual Stock Keeping Units ("SKUs"), reflecting the great diversity of products in the premium cigar market. Reflecting the desire for variety among premium cigar consumers, nearly a quarter of orders for premium cigars contain "sample packs," meaning different combinations of cigars, generally created by the retailers themselves. These sample packs are sold so that premium cigar consumers can (as the name implies) sample a variety of different cigars. Further, premium cigars are most often sold in package quantities of five, 10, 20 and 25.

Overall, the purchasing and sale patterns of premium cigars show that consumers (i) are older; (ii) seek variety in their products; and (iii) purchase only occasionally, in limited quantities, and in seasonal patterns.

4.0 Data Sources and Methodology

Approach

The main purpose of this report is to analyze the purchasing patterns of premium cigar consumers and demographic information relating to the communities where premium cigar consumers live. This type of

analysis requires a data set that is broad and deep enough to generate reliable results. We have combined data from multiple online retailers to create a consistent, merged master data set. The data are linked to Census data to bring in information on demographics and the geographic pattern of purchasers.

Cigar Retailers

We collected transaction level data from five major online retailers: Best Cigar Prices, Cigars International, Famous Smoke Shop, JR Cigar, and Thompson Cigar. Four of the retailers provided data for 2014-2016, inclusive, and all five provided data for 2017. In addition, two retailers provided partial year data for 2018.

SKUs

Each retailer provided detailed information on sales. They reported each transaction, broken down by SKU. A record consists of a SKU, the quantity ordered, the customer number, the order number, the date of the order, date of birth, and geographic information about the customer. An order that consists of three SKUs would have three rows, each with the same order number and customer number. A customer who ordered twice in one year would have two order numbers, but one customer number. Each retailer also provided information on the SKU, including brand, brand family, and other identifying information on the product.

Some retailers identified SKUs as premium brands. Some identified which cigars were "hand rolled," which were also identified as "premium" brands.

Each retailer uses a different system for identifying SKUs, so it is not possible to match a specific SKU from one retailer to a SKU from another retailer. Said another way, a specific package of cigars from one retailer that is exactly the same as a package from another retailer will not have the same SKU and cannot be matched from one retailer to another. Brands, on the other hand, are consistent from one retailer to another, except for house or retailer-specific brands.

We note that using manufacturer's Universal Product Codes (UPC), or barcodes, to match cigars across retailers is not feasible because of two retailer practices. First, it is common for retailers to create new package combinations, for example by packaging smaller quantities, such as one to five cigars that are otherwise identical, or the creation of "sampler" packs that combine different types of cigars, either all from the same brand or from different brands, into a new package. None of these configurations has a manufacturer's UPC code. Second, retailers have "house" brands of cigars that only they sell. These house brands also generally do not have UPC codes.

Customers

Each retailer has a unique customer identification system, which allows us to analyze multiple transactions by a single customer. The identifiers are not common across retailers. It is therefore not possible to perfectly identify customers across retailers, so a customer who purchases from two retailers would be counted as two separate customers in this dataset.

To estimate the potential overlap in customers, we used a combination of location and age. The retailers provided zip codes, in most cases nine-digit zip codes, and date of birth (DOB) for most customers.[1] Using customers' nine-digit zip code and date of birth, we measured how many customers with identical dates of birth shared a nine-digit zip code. Because there are relatively few people in a given nine-digit zip code compared to the number of potential birthdays, this combination is likely to be unique, or close to unique, within a nine-digit zip code. Therefore, any overlap in a nine-digit zip code/DOB combination between retailers is likely to indicate the same customer. In our analysis, approximately 4% of nine-digit zip code/DOB combinations appear in more than one retailer's sales information. This percentage indicates that there is relatively little overlap between customers in the data.

Basic Data Facts

The retailers sell premium and non-premium cigars. In total, the data contain information on more than 12 million orders from more than 2.3 million customers. Importantly, the data illustrate the breadth and depth of the cigar industry, containing over 74,000 SKUs, and an average of approximately 15,000 unique SKUs per retailer. In 2017, over 4 million orders were made by 1.2 million unique customers.

Table 1 - Dataset Summary Statistics, All Years and 2017

Item	Quantity (all years)	Quantity 2017
Total Orders	12,753,862	4,062,002
Total Unique Customers	2,312,552	1,223,926
Total number of SKUs	74,339	54,554
Average Unique SKUs per retailer	14,868	10,911

5.0 Premium Cigars

5.1 Definition of "Premium" Cigar

There are many types of cigars on the market, including both premium and non-premium. Our analysis focuses on premium cigars, which means we need to identify which cigars in the data are premium. As noted above, while there is no federal definition of "premium" cigars, CTP researcher Catherine Corey, in her analysis of data relating to cigar use as reported in Wave 1 of the Population Assessment and Tobacco and Health ("PATH") study, provided guidance on classifying premium cigars that can be adopted and

[1] Because nine-digit zip codes are not required by the postal service, some addresses did not include full zip codes. We used the address verification service from SmartyStreets to standardize addresses to USPS specifications, including full nine-digit zip codes.

adapted to the analysis here.[2] Corey developed criteria for determining what constitutes a "premium" cigar and then applied it to brands included in her analysis. The criteria used is as follows:

> "In general, premium cigars, also referred to as "stogies", consist of more expensive tobacco varieties and components, such as whole tobacco leaf wrapper and binder, and may be assembled by hand."[3]
>
> and
>
> "...information about the brand's tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade), obtained through online searches (conducted fall/winter 2015), was used to distinguish premium cigar brands from non-premium brands."[4]

In our analysis, brands that Corey identified as premium were treated as premium, and brands she considered non-premium were treated as non-premium.[5] Corey's designation of premium versus non-premium cigars nearly perfectly matches industry designations in the data from the retailers who provided such information.

For brands sold by the retailers that Corey did not identify, we followed her approach, as described in the quotes above. For example, we designated hand-rolled cigars as premium. We also conducted internet research on brand descriptions to help determine which were premium.

In total, the brands analyzed by Corey accounted for 30,667 of the SKUs sold by the retailers, leaving 43,672 SKUs to be categorized as premium or non-premium. Of the 30,667 SKUs accounted for in Corey's research, 28,883 SKUs were from brands categorized as premium by Corey, which translates to 149 million cigars. We deemed an additional 41,022 SKUs, out of the 43,672 not addressed by Corey, as premium using the Corey definition and, where necessary, additional research. The brands Corey categorized as non-premium encompassed 1,784 SKUs in our dataset, and we identified an additional

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[2] "The Population Assessment of Tobacco and Health (PATH) Study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the country take part in this study." https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx. The PATH study has over 40,000 participants in the youth and adult cohorts.

[3] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*; Nicotine and Tob. Res. ntx209 (2017).

[4] Corey C, et al., *U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*; Nicotine and Tob. Res. ntx209 (2017) Supplemental Table A.

[5] Two brands, Marsh Wheeling and Optimo, were treated as non-premium even though Corey designated them as premium because their characteristics, including being machine-made, are more similar to non-premium cigars.

2,650 SKUs as non-premium which Corey did not comment on. While the vast majority of SKUs sold by the retailers are premium, nearly half of the cigars sold are non-premium.[6]

Table 2 – Share of Cigar Market Defined by Corey, All Years

	Number of SKUs	Number of Cigars
Premium		
Identified by Corey	28,883	149,195,309
Not identified by Corey	41,022	239,780,128
Total Premium	69,905	388,975,437
Non-Premium		
Identified by Corey	1,784	172,909,021
Not identified by Corey	2,650	178,954,944
Total Non-Premium	4,434	351,863,965
Total		
Identified by Corey	30,667	322,104,330
Not identified by Corey	43,672	418,735,072
Total	**74,339**	**740,839,402**

Once the non-premium SKUs were identified, we excluded non-premium cigar purchases from the analysis. If a transaction contained premium and non-premium SKUs, the non-premium SKUs were dropped, leaving only the premium portion of the order. As such, customers who purchased non-premium cigars exclusively are not analyzed. After accounting for non-premium cigars, our dataset has 11.2 million premium cigar orders, including 3.6 million in 2017. The dataset includes 2.1 million customers, over half of whom made a purchase in 2017. In total, 389 million cigar purchases are represented and almost 70,000 SKUs. Premium cigar purchases for all data received from 2014-2018 totaled $1.1 billion, including $376.6 million in 2017.

[6] Corey et al. classified the brands available in the PATH study, which is a survey, and by definition the brands included would represent only a subsection of premium cigars. The brand data from the five companies includes all brands sold, which is the entire market of brands sold, but with no reference to consumer use of these brands.

Table 3 – Summary Statistics of Premium Cigar Transactions, All Years and 2017

Premium Cigars	All Years	2017
Total Premium Cigar Orders	11,196,240	3,619,014
Total Unique Premium Cigar Customers [7]	2,129,018	1,123,994
Total Premium Cigars Sold	388,975,437	125,314,590
Total Number of Premium Cigar SKUs	69,905	51,123
Average Premium SKUs per Retailer	13,981	10,225
Total Premium Cigar Revenue	$1,142,980,082	$376,556,960

5.2 Share of the Premium Market

As noted, there is no regulatory or other federal government definition of a "premium" cigar and, therefore, no precise way to determine the true size of the premium cigar market. There is, however, a way to approximate the size, by volume, of the premium cigar category. Premium cigars are nearly all imported. Premium cigars are taxed according to weight, and the harmonized tariff codes are assigned to cigars by price. Therefore, analyzing tax and tariff data can approximate the volume of premium cigars sold in the United States. According to this data, as compiled by the Alcohol Tobacco Tax and Trade Bureau, in 2017, there were 351,011,000 cigars imported into the United States that fall into the two highest Harmonized Tariff Categories (HTS) for large cigars.[8] This number is approximate both due to the imprecise nature of using the HTS classifications for premium cigars, and because this number represents premium cigars imported into the US in 2017, not necessarily premium cigars sold in 2017. The data provided by the five online retailers indicated that they sold 125,314,590 premium cigars in 2017.

[7] This number includes customers who purchases both premium cigars and non-premium cigars in the same order, and only excludes those customers who **only** purchased non-premium cigars.

[8] Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau, Statistical Report Tobacco, TTB-S-5210-12-2017, Mar. 5, 2018. This number is most likely artificially inflated as a reference point for premium cigars, however, as the HTS classification is based on price at import and does not discriminate based on cigar characteristics. The 351,011,000 number includes cigars included in the highest two tariff classes, but would likely not be considered premium cigars. It follows that this number can be considered only an approximation of the premium cigar market, and the actual volume of the market is lower than this number.

6.0 Customer Age

Retailers record the birthdate of purchasers, allowing us to calculate the purchaser's age at the date of sale.[9] The data indicate that premium cigar customers of the online retailers are older than the general population. The average age of a cigar customer is 55.3 years and the median age is 57 years. A full 88% were over 35 years old, with almost 55% being over 55 years at the time of purchase, and over 34% being between 35 and 54 years old; approximately 11% were under 34. This distribution skews considerably older than the country as a whole.

Table 4 – Age of Online Premium Cigar Purchasers, 2017[10]

Age Cohort	Customers	Percent	US Population	Percent
18-20	3,928	0.4%	12,774,579	5%
21-24	16,120	1.8%	17,841,890	7%
25-34	84,127	9.4%	45,342,672	18%
35-54	305,443	34.3%	83,250,322	33%
>55	480,814	54.0%	92,854,337	37%
Total	**890,432**	**100.0%**	**252,063,800**	**100%**
Average Age	55.3			
Median Age	57.0		38.0	

A subset of the premium cigar market includes flavored premium cigars. We analyzed the average purchaser age of flavored premium cigars and found that the average age was 52 years old and the median is 53.[11]

7.0 Purchasing Patterns

The dataset of premium cigar transactions allowed for a rich analysis of purchasing patterns. These trends include overall market trends, such as seasonal purchasing patterns and the geographic dispersion of customers, as well as how often customers order and what they order when they purchase premium cigars.

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[9] Retailer data provided date of birth for 83% of the orders, and the age analysis performed here is based on these numbers. We understand that the retailers all now use independent third-party age verification software, ensuring there are no underage sales even if a date of birth is not currently recorded for the customer.

[10] While there were 883,779 premium cigar purchasers in 2017 with age information, there were slightly more, 890,432, ages recorded. This is because a single customer could make multiple purchases in a calendar year before and after their birthdate, resulting in two age entries for that individual.

[11] We undertook a limited study of flavored premium cigars in order to compare the average age of flavored premium cigar purchasers to the whole universe of premium cigar purchasers. In order to identify the flavored premium cigars we started with the brands analyzed in the PATH study and did additional keyword searches in the product name for flavors including "Java", "Vanilla", and "Rum."

7.1 Basic Results

Our dataset captured 11.2 million orders by 2.1 million unique customers, who purchased 389 million cigars. The average price per premium cigar was $2.94, and the average number of premium cigars sold per order was 34.7.

Table 5 – Basic Premium Cigar Purchasing Results

Premium Cigars	All Years	2017
Unique Customers	2,129,018	1,123,994
Orders	11,196,240	3,619,014
Total valid rows (Order-SKU)	18,172,016	6,146,470
Unique SKUs Sold	69,905	51,123
Number of Cigars Sold	388,975,437	125,314,590
Average Number of Cigars per Order	34.7	34.6
	18,172,016	
Avg Price per Cigar	$2.94	$3.00
Avg Amount Spend per Order-SKU Purchase	$62.90	$61.26

7.2 Market Purchasing Patterns

Seasonality

Cigar purchases exhibit significant seasonality. Cigar purchases are lowest in January and February, increase through the spring as Father's Day approaches, and peak in the summer before declining throughout the fall. The only exception to this pattern is a sales surge in November/December in advance of the holiday season. In the peak month, the number of cigars purchased is between 41% and 53% greater than in the month of lowest purchases.

Figure 1 - Cigar Units and Expenditures by Month, 2014-2017

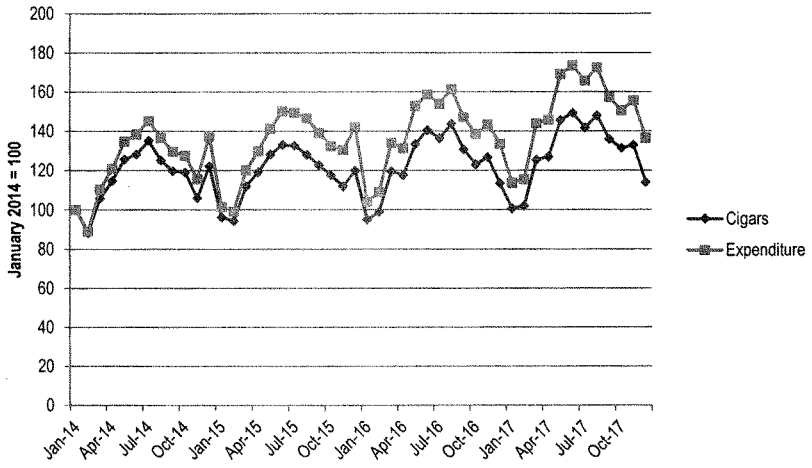


Table 6 – Seasonality of the Number of Cigars Purchased

Year	Peak month	Lowest Month	Ratio
2014	135.15	88.25	1.53
2015	132.99	94.42	1.41
2016	143.47	95.02	1.51
2017	149.17	100.60	1.48

7.3 Frequency

The data cover four full years (2014-2017) of sales for four of the retailers. We examined repeat purchasing patterns over these four years by summing how many times each customer placed an order in that period. A customer who ordered eight times would have eight order numbers in the data assigned to a single customer number. We also measured the number of cigars that each customer purchased. For this analysis we considered only customers who placed orders 240 or fewer times over the four year

period, or approximately once per week.[12] More frequent purchasers were viewed as more likely to be retail stores or other reseller restocking as opposed to end purchasers buying cigars.

For the four retailers over the four years, there were 1,469,334 unique customers and 304,119,528 cigars purchased. Approximately 44% (648,824 out of 1,469,334) customers purchased only once, and accounted for 5% of the cigars ordered. A significant majority of customers, 86 %, ordered 10 or fewer times, but account for only 29% of cigars. In contrast, the 14 % of customers who ordered at least 11 times account for 71% of cigars purchased.

Table 7 – Frequency of Premium Cigar Purchases, All Years

Number of Orders (2014-2017)	Number of Customers	% of Total Customers	Total Cigars Purchased	% of Total Cigars Purchased
1	648,824	44%	14,774,926	5%
2	216,525	15%	11,321,694	4%
3	119,620	8%	9,931,874	3%
4	79,295	5%	9,180,555	3%
5	56,932	4%	8,456,268	3%
6	43,265	3%	7,908,170	3%
7	34,254	2%	7,480,944	2%
8	27,676	2%	6,979,435	2%
9	22,844	2%	6,662,368	2%
10	19,304	1%	6,466,243	2%
Sub-Total – 10 or fewer orders	1,268,539	86%	89,162,477	29%
Tri-Monthly (11-20)	101,427	7%	52,468,590	17%
Bi-Monthly (21-36)	56,717	4%	61,263,292	20%
Monthly (37-60)	28,253	2%	54,970,487	18%
Bi-Weekly (61-120)	13,128	1%	39,736,035	13%
Weekly (121-240)	1,270	0%	6,518,647	2%
Sub-Total – 11-240 orders	200,795	14%	214,957,051	71%
Total 1-240 orders	**1,469,334**	**100%**	**304,119,528**	**100%**

We also analyzed the average order size based on frequency. In general, the more frequently a customer orders cigars, the more cigars, *per order*, the customer purchases. For example, customers who ordered only once in the data purchased 23 cigars on average. Customers who ordered ten times in the data ordered 33 cigars per order on average. The maximum average order size is for customers who purchase

[12] Customers who ordered more than 240 times over the period represent less than 1% of the customers and purchased 1.14% of the total cigars sold.

monthly, and customers who ordered bi-weekly or more frequently ordered fewer cigars, per order, than the monthly purchasers.

Table 8 – Average Number of Premium Cigars Ordered and Order Amount by Order Frequency, All Years

Number of Orders (2014-2017)	Average Cigars per Order	Average Spending per Order
1	23	$75.42
2	26	$85.27
3	28	$89.47
4	29	$92.62
5	30	$94.16
6	30	$96.22
7	31	$97.44
8	32	$99.15
9	32	$100.00
10	33	$101.17
Tri-Monthly (11-20)	35	$105.08
Bi-Monthly (21-36)	40	$111.43
Monthly (37-60)	42	$116.39
Bi-Weekly (61-120)	39	$108.95
Weekly (121-240)	34	$98.63

Most Frequent Purchasers

Approximately 1.1% of cigars were purchased by customers who placed more than 240 orders over four years. Forty-one customers placed a total of 12,144 orders in the period, or an average of 74 orders per customer per year.[13] The average number of cigars per order is 31.9 and the average amount spent per order is $94.85. The average age of these purchasers is 60.9, and the median age is 60.0.

[13] Five customer IDs were dropped from this analysis. Two IDs, "NA" and "00000" appear to include incomplete data entries and do not reflect actual customers. The remaining three IDs place orders with dramatically higher frequency and are removed as outliers. These IDs placed over 3,000 orders over the four years. These five IDs account for 1.02% of the total cigar purchases captured in this dataset.

7.4 Product Quantity

We have analyzed the product quantity of the cigars purchased. There are three main methods by which these retailers sell premium cigars: as single cigars, as sample packs, and as boxes.[14]

Samplers

A sampler is a single SKU that contains more than one type of cigar, and in their product descriptions the retailers identified those SKUs that are samplers. Approximately 25% of orders include at least one sampler SKU. Samplers are a smaller portion of the overall sales, as approximately 13% of premium cigars sold are in samplers, and the other 87% are non-sampler cigars.

Table 9 – Sampler and All Other Orders, All Years and 2017

	All Years		2017	
Type	Number	Percent	Number	Percent
Orders Including Samplers	2,775,109	25%	816,016	23%
Orders Not Including Samplers	8,421,131	75%	2,802,998	77%
Total	**11,196,240**	**100%**	**3,619,014**	**100%**

Table 10 – Premium Cigars Sold in Samplers, All Years and 2017

	All Years		2017	
Type	Number	Percent	Number	Percent
Cigars Sold In Samplers	50,424,486	13%	16,043,731	13%
Cigars Not Sold In Samplers	338,550,951	87%	109,270,859	87%
Total	**388,975,437**	**100%**	**125,314,590**	**100%**

Single Cigars or Boxes

We analyzed the sales with respect to product quantity. Cigars are often thought of as coming in "boxes" of 20 or 25, though box sizes vary widely. For our purposes, a single cigar is a SKU with a single cigar, and multi-pack is a SKU with a quantity of 2 - 4 cigars, and a box is a SKU of 5 or more cigars.

Most orders are focused on boxes as opposed to individual cigars or multi-packs. More than 90% of orders consist only of boxes, as we have defined them. Relatively few orders contain single cigars or multi-packs.[15]

[14] In this report "box" will refer to any product quantity above 5 cigars. A "multipack" refers to packages of 2-4 cigars.

Table 11 – Orders by Mix of Individual Cigars and Boxes, All Years

	# Orders	% Orders of Total	# Cigars	% Cigars of Total
Single Cigar Only	130,275	1.2%	766,671	0.2%
Mulit-Packs and Single Cigar Only	82,545	0.7%	519,107	0.1%
One Box Only, No Single or Multi	7,416,110	66.2%	211,836,839	54.5%
Multiple Boxes, No Single or Multi	3,193,946	28.5%	157,932,618	40.6%
Mix of 1+ Boxes and 1+ Single or Multi	373,364	3.3%	17,920,202	4.6%
Total	**11,196,240**	**100%**	**388,975,437**	**100%**

Table 12 – Order Characteristics by Box Size, All Years

Box Size	Number of Boxes Ordered	Total Number of Cigars	Number of Sampler Cigars	Sampler Cigars as % of Box Size	Total Spent	Avg Price per Box	Avg Price per Cigar
5	6,372,667	31,863,335	5,286,950	16.6%	$141,537,070	$22.21	$4.44
6-9	783,321	5,673,414	2,904,611	51.2%	$23,700,473	$30.26	$4.18
10	2,482,261	24,822,610	6,651,520	26.8%	$108,548,916	$43.73	$4.37
11-19	1,491,336	21,339,045	8,395,120	39.3%	$75,593,806	$50.69	$3.54
20	5,950,477	119,009,540	8,975,660	7.5%	$321,021,901	$53.95	$2.70
21-24	601,098	14,135,911	1,529,362	10.8%	$75,255,014	$125.20	$5.32
25	2,301,634	57,540,850	668,725	1.2%	$201,609,329	$87.59	$3.50

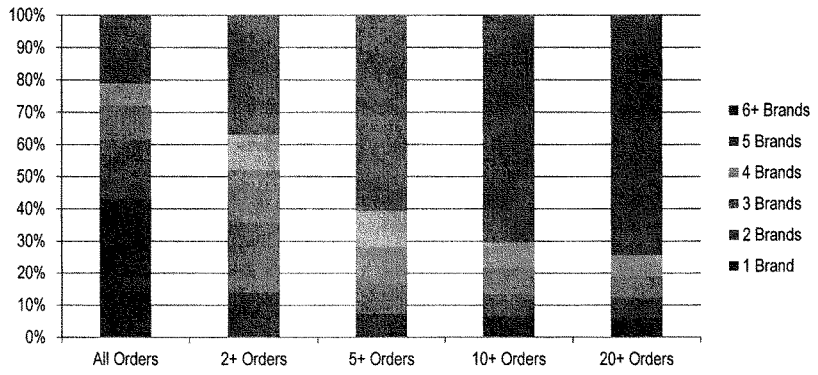
7.5 Brand Variety

We investigated the variety of brands purchased by customers by summing the total number of brands an individual customer purchased. For all customers, more than 60% purchase one or two brands. However, this statistic disguises the behavior of more frequent cigar purchasers. For customers who order at least twice, approximately 36% order one or two brands. For customers who order at least 10 times, only 13% order one or two brands. As indicated in Figure 2, the more frequently a customer purchases, the more brands the customer purchases in total. Put another way, frequent customers purchase a variety of cigars, more so than less frequent customers.

[15] The most popular product quantity configurations, based on number boxes ordered, are (i) a five cigar "box," (ii) a twenty cigar box, (iii) a 10 cigar "box," and (iv) a twenty-five cigar "box." We understand that many of the five and ten cigar configurations contained in the data are actually "packs" of five or ten that generally have been created by the retailers from the original boxes of 20 or 25. For ease of analysis we have included these "packs" in the "box" category.

The majority of the time, sampler packs are created by the retailer and listed in our dataset under a single SKU. As such, they are considered one "brand" in this chart, even though the SKU contains multiple brands of premium cigars.

Figure 2 – Number of Brands Ordered by Order Frequency



8.0 Geocoding and Geographic Information

8.1 Geographic Data from Retailers

The retailers provided geographic information on the shipping address for each order. The type of information provided varied by retailer. Some retailers provided a mailing address, while others disclosed the nine-digit zip code associated with the order.

Where address data was available, the addresses were geocoded to give the precise longitude and latitude (XY coordinates) of the location. In order to geocode the data, we tested a sample set of addresses using two geocoding services, and observed the accuracy scores of each.

There are many providers that offer geocoding services. To find the best service for our analysis, we selected two providers, Geocodio and Texas A&M GeoServices (an affiliate of Texas A&M University Department of Geography), to geocode sample datasets. When the sample data set was analyzed, Geocodio located 93% of the addresses with an accuracy score above 90%, whereas Texas A&M GeoServices matched 86% of addresses with an accuracy score above 90%. On the basis of this analysis, we used Geocodio to geocode all the addresses in our dataset, of which 90% were geolocated with an accuracy score above 90%.

In instances where nine-digit zip code data was provided, we matched zip codes to geographic coordinates using a database purchased from GreatData.com.[16] With this database, we were able to assign coordinates to the provided nine-digit zip codes.

The full data set of all premium cigar purchases includes 2,234,584 customer addresses and nine-digit zip codes, which includes instances where multiple addresses and/or nine-digit zip codes are associated with a single customer ID. Of these, 85% are valid addresses or nine-digit zip codes, and 95% of the valid addresses or nine-digit zip codes were successfully geocoded to a Census Tract.

Table 13 –Premium Cigar Customers Successfully Matched to Census Tracts

Total Addresses or 9-Digit Zip Codes Associated with Premium Purchases	2,234,584
Valid Addresses or 9-Digit Zip Codes	1,899,527
Valid Addresses or 9-Digit Zip Codes as Percent of Total	85%
Addresses or 9-Digit Zip Codes Geocoded to a Census Tract	1,796,341
Percent of Valid Addresses or 9-Digit Zip Codes Geocoded	95%

Linking to Community Data

We used the geographic data provided by the retailers to understand the geographic distribution of cigar purchasers and to identify the community characteristics of the Census Tract of the purchaser. This geographic information provides insight into the distribution of cigar purchasers throughout the country, including the weighting of purchasers by state and in rural or urban areas. Further, by geocoding the addresses, we were able to identify the Census Tract of the purchaser. With the Census Tract, we were able to link a purchaser to community data, such as median household income and education.

With the geographic coordinates of consumers, we were able to identify the Census Tract of the location, providing demographic information from the US Census about the socioeconomic status of their community.

8.2 Geography

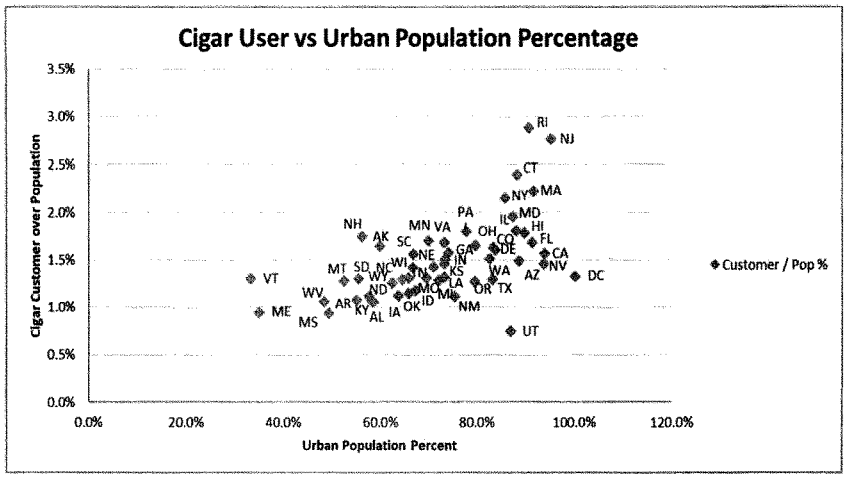
Cigar purchases are correlated with geography as well. More urbanized states have more cigar purchasers, relative to population, than more rural states. Figure 3 plots penetration of cigar purchasers against the urban population. Each dot is a state. States in which most of the population lives in urban

[16] GreatData.com uses the latest United States Postal Service database to match nine-digit zip codes to their latitude and longitude coordinates. A nine-digit zip code usually refers to a segment of one side of a street and can contain multiple addresses, but it can also be assigned to a single building or cluster of buildings. As such, they cannot be used to find an exact location, but they do provide a good approximation of an address's location. https://greatdata.com/product/51/zip4-geo

areas, as defined by the Census, are on the right side of the figure, and more rural states are on the left side of the figure. States with many cigar purchasers relative to population are on the top of the figure, and states with few purchasers relative to population are lower on the figure. For example, Washington DC is 100% urban, so it is on the far right side of the figure.[17]

The dots in the figure generally slope up, which means that the more urban states, in general, have higher percentages of cigar purchasers than states that are less urban. The one obvious outlier is Utah, which is nearly 90% urban but has relatively few cigar purchasers. The skew towards urban sales is somewhat unexpected, given the fact that urban customers have access to competing bricks and mortar cigar retailers. However, as is seen in the next section, premium cigar purchasers tend to live in higher income communities, which also skew urban.

Figure 3 – Percent of Population Purchasing Premium Cigars by State's Urban Population



[17] The customer list includes all customers. There may be some overlap, as an individual who orders from multiple retailers will be included in the calculation twice. Because this overlap can occur in any state, and is relatively minor to begin with, the overall pattern will be the same had it been possible to de-duplicate the customer list. As discussed above in Section 4, there is only an approximate 4% overlap of customers between the retailers.

8.3 Demographics

Retailers do not collect personal data about customers, preventing us from commenting directly on characteristics of purchasers beyond age and geographic location. By identifying the Census Tract in which a consumer resides, however, we can analyze the community they live in. By design, Census Tracts contain a small number of people, with an optimum population of 4,000.[18] As such, Census Tracts serve as a useful measure of the characteristics of premium cigar purchasers. In this section we look at the median income and education attainment in the Census Tracts of premium cigar purchasers.

8.4 Income

Overall, the Census Tracts of premium cigar purchasers have higher incomes than the general population. The median household income in the Census Tracts of premium cigar purchasers is $65,573. By comparison, nationally, median household income is $57,617. Over 15% of customers live in tracts with median household income above $100,000, whereas 10% of households nationally are in that bracket.

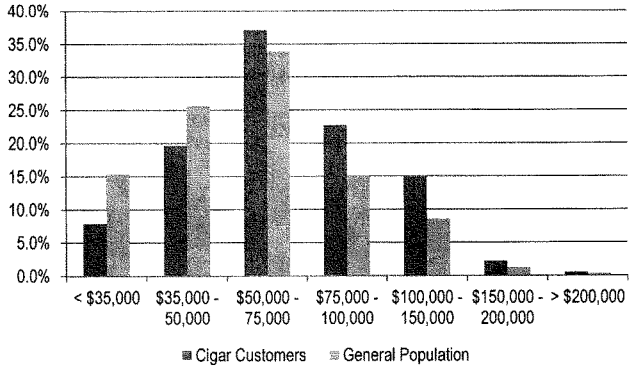
Table 14 – Median Household Income of the Census Tract of Premium Cigar Purchasers

Income Category	# Customers	Percentage	Total Population in these CT	% of US Pop Census Tracts
< 35,000	140,443	7.8%	38,154,387	15.4%
35,000 - 50,000	352,466	19.6%	63,370,525	25.6%
50,000 - 75,000	665,660	37.1%	83,951,957	33.9%
75,000 - 100,000	407,767	22.7%	37,317,707	15.1%
100,000 - 150,000	267,903	14.9%	21,300,987	8.6%
150,000 - 200,000	39,382	2.2%	2,993,843	1.2%
> 200,000	7,832	0.4%	618,297	0.2%
Median HH Income	$65,573			
Mean HH Income	$71,633			
US Median HH Income	$57,617			

Source: US Census Bureau, American Community Survey 2016 5-year Estimates

[18] US Census Bureau, 2010 Geographic Terms and Concepts, https://www.census.gov/geo/reference/gtc/gtc_ct.html

Figure 4 –Distribution of Median Income of the Census Tracts of Premium Cigar Purchasers and the US Population

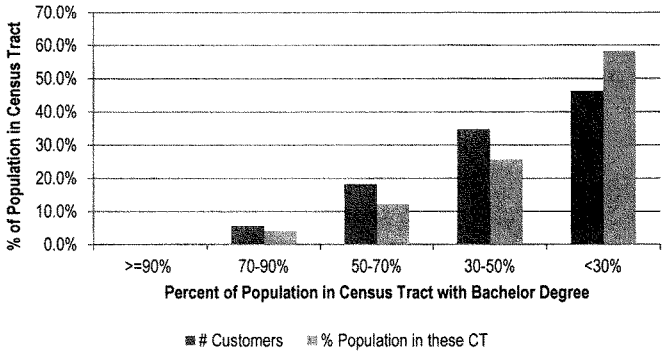


Source: US Census Bureau, American Community Survey 2016 5-year Estimates

8.5 Education

Premium cigar purchasers live in more educated Census Tracts than the general population. Nearly 60% of the general population lives in Census Tracts where less than 30% of the population has a bachelor degree. In contrast, approximately 45% of premium cigar purchasers live in similar tracts. Over 20% of premium cigar purchasers live in tracts where over 50% of the population has a bachelor degree, compared to approximately 15% of the general population.

Figure 5 - Percent of Population 25 and Above with a Bachelor Degree, Census Tracts of Premium Cigar Purchasers and the US Population



Source: US Census Bureau, American Community Survey 2016 5-year Estimates

9.0 Conclusion

The data from these five retailers show consistent trends and data about both premium cigar purchasers themselves, and their purchasing patterns.

- First, premium cigar purchasers are an older population, with an average age of 55 and a median age of 57.
- Second, premium cigar purchasers reside in areas with higher levels of education and higher incomes than the rest of the US population.
- Third, premium cigar purchasers are, for the most part, infrequent purchasers of premium cigars. Only 17% of purchasers place more than, on average, two orders per year.
- Fourth, premium cigar purchasers reliably purchase orders containing sample packs or five packs of cigars.
- Fifth, repeat purchasers of premium cigars show little brand loyalty.
- Sixth, premium cigars purchases spike at certain times of the year, rather than being spread evenly over the year.
- Finally, the premium cigar market has incredible diversity, with a current average of approximately 10,000 SKUs per retailer.

Overall, premium cigar purchasers are older, live in communities that are wealthier and better educated than the average population, and are not purchasing premium cigars on a regular and consistent basis.

Appendix A

ESI ECONSULT SOLUTIONS INC.

economics | policy | strategy

Richard P. Voith, Ph.D.

President and Principal

Dr. Voith is a well-known expert in real estate economics, transportation, and applied microeconomics. As president and founding principal of Econsult Solutions, Dr. Richard Voith oversees a wide variety of projects in the realm of housing, labor markets, transportation, and economic development. Just as importantly, Dr. Voith is involved in setting the strategic direction of organizations both large and small. Also, he regularly provides analysis and testimony in support of litigation in real estate and transportation matters.

Areas of Expertise

- Real Estate Economics
- Transportation
- Applied Microeconomics
- Funding for Transit Systems
- Energy
- Metropolitan Development

Education

PhD in Economics
University of Pennsylvania

MS in Energy Management and Policy
University of Pennsylvania

BS in Economics
Haverford College

Experience

Prior to joining Econsult Solutions, Dr. Voith held the position of Economic Advisor at the Federal Reserve Bank of Philadelphia.

Dr. Voith has worked frequently in the public policy arena. In 2013, he was a principal author of *Understanding SEPTA's Statewide Economic Value* which demonstrated the importance of transportation investment for the state. In 2006, Dr. Voith was appointed by Governor Rendell to the newly created Transportation Funding and Reform Commission charged with recommending appropriate levels of funding for transit systems, roads and bridges. Dr. Voith is also a member of the SEPTA Board of Directors, serving as Vice Chairman of SEPTA from 1996 to 1998.

Professional, Corporate, Civic Leadership

Dr. Voith is a founding board member of Pentrans, an organization dedicated to balanced, multimodal transportation and mobility alternatives in Pennsylvania. Dr. Voith is active in Philadelphia area organizations, including Philadelphia Youth Basketball, an organization which is focused on the holistic development of Philadelphia youth.

Additional Experience

Dr. Voith has taught *Cost Benefit Analysis* at the Wharton School's Business and Public Policy Department, and *Urban Real Estate Economics* through the Wharton's Real Estate Department. Dr. Voith continues as a Faculty Fellow at the University of Pennsylvania's Institute for Urban Research.

Over the last 15 years, Dr. Voith has served on several National Academy of Science Foundation Advisory Panels addressing topics such as the interrelationships between highway and transit investment and land use, valuing the costs and benefits of transit investments, and the relationships between land use and public health. He has been a guest speaker at numerous forums, including those sponsored by the Lincoln Land Institute, the Brookings Institution, Urban Land Institute, and the Department of Housing and Urban Development. Until 2007, Dr. Voith served on the editorial board of Real Estate Economics.

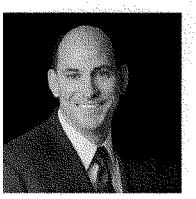
Contact
Email: voith@econsultsolutions.com
Phone: 215-717-2777

Econsult Solutions, Inc.
1435 Walnut Street, 4th Floor
Philadelphia, PA 19102
econsultsolutions.com

Appendix B

ESI ECONSULT SOLUTIONS INC.

economics | policy | strategy



Peter A. Angelides, Ph.D., AICP

Principal

Dr. Peter Angelides is principal of Econsult Solutions, Inc. (ESI) and a member of the teaching faculty at the University of Pennsylvania. Dr. Angelides has high-level expertise in both economics and city planning, applying critical economic thinking to projects in real estate, economic development, transportation, tax policy, valuation and litigation. He assists clients in many industries, including real estate development, transportation, local and regional government, affordable housing, gaming, utilities, health care, and insurance.

Areas of Expertise

Real Estate

Transportation

Economic Development

Tax Policy

Gaming

Litigation

Education

BA in Urban Studies
University of Pennsylvania

Masters in City Planning
University of Pennsylvania

MS, PhD in Economics
University of Minnesota

Experience

When he joined ESI, Dr. Angelides brought a wealth of experience in both economics and planning. Prior to joining ESI, he practiced economics in the private sector having worked for large and small firms including:

- Econsult Corporation, Vice President and Director;
- PricewaterhouseCoopers, Philadelphia PA, Director;
- Charles River Associates, Washington, DC, Economist;
- Putnam Hayes & Bartlett, Washington, DC, Economist.

In these roles he evaluated market competitiveness in merger and rate-setting proceedings before several federal regulatory agencies, estimated the economic impacts from private investment, set prices for intellectual property, evaluated the impact of technology licensing agreements and calculated damages in numerous commercial disputes.

Dr. Angelides practiced planning in the public and private sectors having worked for:

- Wallace Roberts and Todd;
- The Central Philadelphia Development Corporation;
- Philadelphia City Planning Commission.

Professional, Corporate, Civic Leadership

Dr. Angelides serves as a board member or in other contributing roles for several civic and professional organizations, including:

- Design Advocacy Group;
- Philadelphia Historic Preservation Task Force;
- PenTrans;
- Urban Land Institute;
- The Transportation Research Board;
- American Institute of Certified Planners (AICP);
- Racquet Club of Philadelphia.

Additional Experience

Dr. Angelides teaches courses in the areas of urban economics, public finance, and infrastructure investment at the University of Pennsylvania in both the Department of City and Regional Planning, and at the Fels Institute of Government.

Contact

Email: angelides@econsultsolutions.com

Direct: 267-687-0210
Office: 215-717-2777

Econsult Solutions, Inc.
1435 Walnut Street, 4th Floor
Philadelphia, PA 19102
econsultsolutions.com

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

EXHIBIT C

July 24, 2018

Premium Cigars:

What is known about patterns of use and about health effects?

Geoffrey Kabat, Ph.D. M.S.[1]

Introduction

On March 26, 2018, the Food and Drug Administration ("FDA") issued an Advance Notice of Proposed Rulemaking ("ANPRM") regarding the regulatory status of premium cigars. In the ANPRM, FDA requested data regarding the "use patterns of premium cigars" and data and information regarding "public health considerations associated with premium cigars." (83 Fed. Reg. at 12,903).

The purpose of this review is two-fold: (i) to describe what is known about prevalence of use of premium cigars, and (ii) to describe what is known about the health effects of cigar smoking generally and, particularly, of premium cigars.

Prevalence of Use of Premium Cigars

Little work has been done to specifically study users of premium cigars. There are, however, three recent studies analyzing recent tobacco usage data that contain relevant information regarding premium cigar usage prevalence (1-3). These three studies are analyzed below.

The most recent data analyzing use patterns of tobacco products is the Population Assessment of Tobacco and Health (PATH) study, a national longitudinal study of tobacco use and health. Started in 2013, the PATH study is the first large research effort undertaken by the National Institutes of Health and the Food and Drug Administration. As such, it uses data acquired by the government.

Kasza, Ambrose, Conway et al. looked at Wave 1 of the PATH study to examine tobacco product use by youth and young adults (1). While "premium cigar" itself was not defined in the PATH dataset, the survey collected data and information regarding "traditional cigars." "Traditional cigars" were defined as "contain[ing] tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta and Arturo Fuente, but there are many others." All of the brands specified are premium cigars. Thus, the "traditional cigar" category in this survey has a large degree of overlap with premium cigars. **This**

[1] My CV is attached as Exhibit A.

study showed that only 0.4% of the adult population used traditional cigars "frequently" (Supp. Table S4). "Frequent use" was defined as "at least 20 of the past 30 days." For youth, no frequent use of traditional cigars could be reliably reported (Supp. Table S4). This indicates that youth are not using premium cigars.

One of the first studies to report data on usage of premium cigars in particular was the National Adult Tobacco Survey (NATS) in 2012-2013 (2). In this study, premium cigar smokers were defined as "those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder or wrapper" (2). Among usual premium cigar smokers, 3.3% reported "every day" use, 25.6% reported "some day" use, and 71.2% reported "rarely." **This means that 96.7% of premium cigar smokers smoke premium cigars on less than a daily basis.** Regarding dual use of cigars with cigarettes, 75.2% of little filtered cigar smokers also smoked cigarettes, 58.3% of usual cigarillo/mass market cigar smokers also smoked cigarettes, whereas only 35.1% of premium cigar smokers also smoked cigarettes. Overall, premium cigar *smokers were much less likely to smoke cigarettes compared to smokers of other* types of cigars. Finally, it is clear that premium cigar smokers are older -- only 15.1% of cigar smokers aged 18 to 29 years old smoked premium cigars.

Corey, Holder-Hayes, Nyugen, et al. (3) also presented information from Wave I of the PATH study on smoking patterns among adult current established smokers of different cigar types and cigarettes. In addition to cigarillos and filtered cigars, "traditional cigars" were divided into "premium" and non-premium" cigars. Since there are no regulatory definitions of premium cigars, the authors used information about the brand's tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade) to identify premium cigars. Premium cigar smokers were substantially older at first regular use of a tobacco product than other smokers (24.5 years compared to 16.6 -19.5 years for cigarettes, cigarillos and non-premium cigars). **Overall, 0.7% of adults smoked premium cigars.** Although smokers of premium cigars had comparable lifetime consumption compared to smokers of other tobacco products (Table 2), they differed markedly from smokers of other products on four important smoking parameters: (i) whether they smoked every day, (ii) median number of days smoked in the past 30 days, (iii) number of cigars smoked per day, and (iv) whether they currently smoked cigarettes. These differences were all in the direction of lower consumption. For example, **only 6.7% of premium cigar smokers reported smoking every day,** compared to 25.3% of non-premium cigar smokers, 22.0% of cigarillo smokers, 37.3% of filtered cigar smokers, and 79.5% of cigarette smokers. **The median number of days smoked in the past 30 days was 1.7 among premium cigar smokers**, 9.2 among non-premium cigar smokers, 7.5 among cigarillo smokers, 14.0 among filtered cigar smokers, and 29.4 among cigarette smokers. **The median number of premium cigars smoked per day was 0.1**, compared to 0.4 for non-premium cigars, 0.3 for cigarillos, 1.6 for filtered cigars, and 10.0 cigarettes per day for cigarette smokers. **Dual use of cigarettes was markedly lower among**

premium cigar smokers compared to smokers of other types of cigars and other non-cigarette tobacco products (Table 4).

The three papers that present prevalence data on the use of premium cigars are consistent in indicating that:

- there is no measurable use of premium cigars by youth;
- users of premium cigars tend to be older at first regular use;
- the overwhelming majority of premium cigar smokers do so on a non-daily basis -- 93.3% according to PATH, and 96.7% according to NATS;
- frequency of use is extremely low – the median number of days smoked in past 30 days is 1.7, and the median amount smoked is 0.1 cigars per day.

Association of cigar smoking with disease mortality and incidence.

Four studies since 2014 have examined the association of cigar use with health outcomes (4-7). These studies differ in the level of detail regarding smoking behavior. For example, none of these studies differentiate between types of cigars. Further, most studies do not provide information regarding specific frequency of cigar smoking, or the amount smoked per day on days smoked. Three of the studies examined the association of cigar use and mortality (4-6), and one examined the association of cigar use with cancer incidence (7).

Christensen et al. (4) is the most probative of this group of studies due to its examination of cigar only users, and its division of this population into non-daily and daily smokers. Christensen et al. used data from the National Longitudinal Mortality Study to examine the mortality risk associated with cigarette, cigar, and pipe smoking among 357,420 participants who reported exclusively using cigars, pipes, or cigarettes or reported never using any type of tobacco product. Participants provided tobacco use information at baseline in surveys beginning in 1985 and were followed for mortality through the end of 2011. A total of 51,150 deaths were recorded during follow-up. **Among non-daily cigar users there were no increased risks for mortality from tobacco-related cancers (tobacco related cancers HR 1.08, 95% CI 0.45-2.61) and there was no increased risk for lung cancer (HR 0.74, 95% CI 0.08-7.26). Further, for non-daily cigar smoking, no increased health risks were reported for oral cancer, cerebrovascular disease, respiratory or COPD. Additionally, no deaths were reported for any cigar smoking, daily or non-daily, for oral cancer** (Table 3). Compared to never users of tobacco, exclusive, daily cigar smokers as a group had higher total mortality (HR 1.20, 95% CI 1.03-1.38) and higher mortality from tobacco-related cancers (including oral cavity, esophagus, larynx, lung, bladder, and pancreas). Among daily cigar users, mortality risks (hazard ratios [HR]) from tobacco-related cancer (HR 1.80, 95% CI 1.20-2.69), lung cancer (HR 4.18, 95% CI 2.34-7.46), and COPD (HR 3.29, 95% CI 1.33-8.17) were elevated and statistically significant (Table 3).

As mentioned, limitations of this study include: lack of detailed information on specific frequency of cigar use (only daily/non-daily and exclusive/non-exclusive), no information on amount smoked per day, no inhalation information, and the fact that the type of cigar smoked was not distinguished. The age range of the study population was 35-80. The main strength of this study is that it provides information on the mortality risk associated with both daily and non-daily exclusive cigar smoking. As nearly all premium cigar smokers are non-daily smokers, this study is of particular relevance.

Chang et al. (5) conducted a systematic review of studies of cigar smoking and all-cause and smoking-related mortality. They included 22 studies from prospective cohorts. These cohort studies were initiated in the twentieth century, when smoking habits were very different from what they are today. The study populations included in this systematic review were mainly white middle-aged men in North America and Europe who smoked cigars in the 1960s or earlier. At that time, the predominant cigar type studied was the "large cigar," whereas today the U.S. cigar market consists of products manufactured with various shapes, sizes, tips, filters and packaging. The focus was on current cigar smoking at baseline. "Primary cigar" smokers (i.e., current exclusive cigar smokers with no previous history of cigarette or pipe smoking) were distinguished from "secondary cigar" smokers (i.e., current exclusive cigar smokers with a previous history of cigarette or pipe smoking).

Although the systematic review included data from 22 studies, only two studies provided information on mortality risks by amount smoked and by inhalation. In the Dorn study, the lowest level of cigar use listed was less than five cigars per day. At this level of cigar smoking, there was no suggestion of increased risk of all-cause mortality 1.04 (95% CI 0.98-1.11) (Table 3). In CPS-I, the lowest level of cigar smoking was 1-2 cigars per day. The hazard ratio for this category was 1.02 (95% CI 0.97- 1.07), again showing no increased risk. The CPS-1 study also presented data on risk estimates for inhalation levels in relation to all-cause mortality in primary cigar smokers. For the "no inhalation" category among daily primary cigar smokers, the risk estimate was 1.04 (95% CI 1.00-1.08) suggesting little increased risk. While these two studies did report on mortality risks by amount smoked and by inhalation, they did not present any data for cigar smokers smoking less than one cigar per day. The other 20 studies similarly did not provide this data.

A large number of results are reported in this paper for the different studies, the different outcomes, and exclusive cigar smoking versus non-exclusive cigar smoking. Owing to different categories of exposure reported in the 22 studies, it was not possible to perform a meta-analysis by level of exposure, which would have provided more precise estimates of the risk associated with different usage patterns. As noted above, the review did not present any results regarding "occasional" or "rare" cigar smoking, or smoking less than one cigar per day.

Nonnemaker et al. (6) estimated mortality from regular cigar use, using data from that National Adult Tobacco Survey, relative risks from the American Cancer Society's Cancer Prevention Studies I and II, and annual U.S. deaths from the National Vital Statistics System. They estimated that regular cigar smoking was responsible for approximately 9,000 premature deaths among U.S. adults aged 35 years or older in 2010. The goal of this analysis was to estimate the impact of cigar smoking on mortality and economic costs (years of potential life lost, etc.). The main analysis focused on current cigar smokers who reported smoking cigars on at least 15 of the past 30 days. The rationale for using this figure given by Nonnemaker et al. is that this is the level of smoking that corresponds to the RRs [relative risks] used in their analysis. Importantly, however, no breakdowns were provided by type of cigar or specific frequency of use, and the threshold used by the authors – smoking cigars on at least 15 of the past 30 days -- is not applicable to use of premium cigars, since, as noted above, premium cigar smokers are overwhelmingly non-daily smokers; in the PATH study, premium cigar smokers smoked on average 1.7 days out of 30. **Thus, the mortality estimates derived in the Nonnemaker et al. paper are not pertinent to the use of premium cigars.**

In addition to the three mortality studies described above, Malhotra et al. (7) carried out a pooled analysis of five cohort studies (one from the Netherlands, one from Australia, and three from the U.S.) to examine the association of exclusive cigar use and predominant lifetime cigar use with risk of smoking-related cancers. Participants enrolled in the five cohort studies were in their late fifties and early sixties. "Ever cigar smokers only" (i.e., smoked cigars currently or in the past, but not cigarettes) had increased risks for all smoking–related cancer (HR 1.47, 95% CI 1.34-1.61), head and neck cancer (HR 1.40, 95% CI 0.98-2.00), and lung cancer (2.73, 95% CI 2.06-3.60), as well as for all cancers (HR 1.07, 95% CI 1.02-1.16). Both exclusive and predominant cigar smokers had increased risks of head and neck cancer, lung cancer, gastric cancer, and kidney cancer, as well as all cancers. These results as reported, however, cannot – for several reasons -- be applied to premium cigars. First, none of the five underlying studies had data on frequency of cigar smoking, therefore the pooled analysis could not present data stratified by frequency of cigar smoking. Second, this analysis does not include any information on the type of cigar smoked. Third, it does not provide any data on the number of cigars smoked per day. Fourth, it provides no age breakdown of the subjects, including age at initiation and (if applicable) cessation, Given these limitations, the Malhotra et al. paper is of questionable use in assessing the risks associated with premium cigars.

There has been one study, and one abstract, published regarding biomarkers of tobacco smoke exposure among cigar smokers. Chen et al. (8) looked at biomarker data in participants in the National Health and Nutrition Examination Survey (NHANES) 1999-2012. They examined biomarkers of tobacco smoke exposure among cigar smokers, smokers of other tobacco products and non-tobacco users in over 25,000 participants. Cigar smokers were classified as either primary cigar smokers or cigar-only smokers, and were further classified as daily or non-daily

cigar smokers. Among both non-daily and daily smokers, both primary cigar smokers and cigar-only smokers had elevated concentrations of serum cotinine and urinary NNAL compared to non-tobacco users. The concentrations were lower, however, than those seen in secondary cigar smokers (i.e. those also using cigarettes) and cigarette smokers. Studies on biomarker data are subject to limitations including that a biomarker measurement obtained at one point in time cannot necessarily be used to characterize a person's habitual level. Further, biomarker data tell us nothing about long-term exposure. Additionally, this study had no information on the type of cigar smoked or on levels of inhalation, which further limits its usefulness. The abstract by Chang et al. (9) reported on biomarkers of urinary metabolites and tobacco-specific nitrosamines in adult cigar smokers in the PATH study (all cigars, and separately for traditional cigars, cigarillos, filtered cigars, cigarettes and non-smokers). This study had very small number of smokers of different types of cigars.

Taken together, the epidemiologic studies described above show that there is no association between non-daily, exclusive smoking of cigars and an increased risk for smoking-related cancers, or an increased risk of death from all causes and certain specific causes. The results from different studies show a fair degree of consistency.

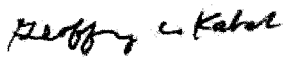
Conclusion

In 1998, NCI Monograph 9 (10) concluded that in relation to all cigars "as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year. This difference in frequency of exposure translates into lower disease risks." (p. iii). The present report has addressed new literature both on use patterns and health risks specific to premium cigars, and comes to similar conclusions based on better and more recent data.

The pattern of use of premium cigars is distinct from that of other types of cigars and far removed from use patterns of cigarettes. Adult prevalence of premium cigar use is extremely low (0.7% in the PATH study), and users are overwhelmingly non-daily users (93% in PATH and 97% in NATS). In addition, compared to other tobacco users, premium cigar smokers smoked fewer days in the past 30 days (1.7 days), smoked few cigars per day on the few days they smoke (0.1 cigars), and were less likely to be current cigarette smokers. Furthermore, these cigars tend to be used by an older population. All of these features point to the risk from premium cigar use being substantially lower than that associated with other types of cigars.

No information is available bearing directly on the health risks of smoking premium cigars. When we examine the most informative prospective studies providing information on current cigar use and mortality (4,5), we see that there is no indication of an increased risk for daily smokers of all types of cigars combined in the lowest category of amount smoked (1-2 cigars per day or less than five cigars per day)(5). Furthermore, in the study by Christensen et al. (4), there is no

indication of an increased risk among non-daily cigar smokers for tobacco related cancer or lung cancer (Table 3). **Taken together, these studies lead to the conclusion that there is no association between non-daily premium cigar smoking -- which applies to the overwhelming majority of premium cigar smokers -- and increased health risks compared to non-smokers.**



Geoffrey Kabat, Ph.D., M.S.

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EXHIBIT A

GEOFFREY C. KABAT, Ph.D., M.S.

16 Bon Air Avenue
New Rochelle, New York 10804-3205

E-mail: gckabat@gmail.com

PROFESSIONAL AND RESEARCH EXPERIENCE:

7/2018-present	Independent scientist; author.
2006 – 6/2018	Senior Epidemiologist, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY 10461-1602.
2001 - 2006	Independent consultant in epidemiology; consultant to UCLA School of Public Health.
1996 - 2001	Associate Professor, Department of Preventive Medicine, School of Medicine, State University of New York at Stony Brook, Stony Brook, NY 11794-8036.
1993 - 1996	Cancer Investigator, Cancer Research Center, Albert Einstein College of Medicine, Bronx, NY.
1992 - 1996	Associate Professor, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, New York, 10461-1602.
1982 - 1992	Senior Epidemiologist, American Health Foundation, New York, New York 10017.
1984 - 1986	Senior Staff Associate, Division of Epidemiology, School of Public Health, Columbia University, New York.
1982 - 1984	Senior Staff Associate, Comprehensive Cancer Center, Columbia University, New York.
1978 - 1981	Associate Epidemiologist, American Health Foundation.
1977 - 1978	Technical Writer, American Health Foundation.

EDUCATION:

1984 Columbia University, New York, NY M.S. Epidemiology

1976 Columbia University, New York, NY Ph.D. Slavic Languages and Literatures

1970 Columbia University, New York, NY M.A. Slavic Languages and Literatures

1967 Haverford College, Haverford, PA B.A. French, Classics

HONORS AND FELLOWSHIPS:

2009	*Choice* Outstanding Academic Title (*Hyping Health Risks*)
1971 - 1972	International Research and Exchange (IREX) Graduate Fellowship for study in the Soviet Union (Leningrad).
1968 - 1971	Faculty Fellowship, Columbia University
1967 - 1968	Woodrow Wilson Fellow, Stanford University
1967	Phi Beta Kappa, High Honors in French, Haverford College

CONSULTANTSHIPS:

Consultant to distilled alcoholic beverages trade association group, DISCUS. Prepared report titled "Assessment of the carcinogenicity of alcoholic beverages under two sets of guidelines: OSHA and American Council of Industrial Hygienists (ACIH)," 1979.

Consultant to Bristol-Myers on cancer statistics, 1982.

Extensive discussions with statisticians at Warner-Lambert concerning results of American Health Foundation epidemiologic studies of the association of mouthwash use and oral cavity cancer (1982-83).

Independent consultant to Weinberg Group, Inc., Washington, D.C. Researched and wrote report entitled: "A Critical Appraisal of Epidemiologic Studies of Alcohol Use in Relation to Cancer Risk" (1991-92).

Served as consultant to the Environmental Protection Agency's Science Advisory Board Committee on the Health Effects of Environmental Tobacco Smoke (December 4-5, 1990 and July 21-22, 1992).

Senior Consulting Investigator to "Environmental Tobacco Smoke and Mortality among CPS I," P.I. Dr. James Enstrom, UCLA, 1997-2006.

Consultant in nutritional epidemiology on "Pubertal development in a multi-ethnic population of nine-year-old girls," Dr. Mary S. Wolff, Mount Sinai School of Medicine, NY, 2001-2002.

Consultant in nutritional epidemiology on "Intake of folate and other B-vitamins and risk of breast cancer," Dr. Jia Chen, Mount Sinai School of Medicine, NY, 2002.

REVIEWER FOR JOURNALS:

American Journal Epidemiology

Annals of Epidemiology

BMJ

BMC Cancer

Cancer

Cancer Causes and Control

Cancer Epidemiology

Cancer Epidemiology Biomarkers Prevention

Cancer Research

Epidemiology

European Journal of Cancer and Clinical Oncology

International Journal of Cancer

International Journal of Epidemiology

International Journal of Environmental Research and Public Health

Journal of the American Medical Association

Journal of the National Cancer Institute

Journal of the South Carolina Medical Association

Lung Cancer

New England Journal of Medicine

Nicotine and Tobacco Research

Nutrition and Cancer

Preventive Medicine

Regulatory Toxicology and Pharmacology

LANGUAGES:

Fluent in French and Russian; working knowledge of Japanese and German.

PUBLICATIONS:

Total publications: >150; total citations: 8,879; H-index: 54.

Peer-Reviewed Feature Length Articles:

1. Wynder EL, **Kabat GC**. Opportunities for prevention of cancer in blacks. *Prog Clin Biol Res* 1981;53:237-252.

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Advisory Role:

Genetic Literacy Project – Board of Directors

https://www.geneticliteracyproject.org/our-team/

American Council on Science and Health – Advisor http://www.acsh.org/our-team

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7/19/2018

Appendix 2

CIGAR ASSOCIATION OF AMERICA, INC.

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

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

www.cigarassociation.org

February 5, 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: Docket No. FDA-2017-N-5095

Dear Sir or Madam:

The 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 hand-made 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 continue to conduct business.

On May 10, 2016, FDA published the Final Rule, to "deem all products that meet the definition of 'tobacco product' under the law...and subject to the tobacco control of the FD&C Act"; the Agency also outlined how it intended to regulate these tobacco products.[1] The breathtaking scope of the Final Rule together with a

[1] Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule. 81. Fed. Reg. 28,974 (May 10, 2016) ("Final Rule").

clearly unreasonable timeline and lack of specificity of what is required has led to numerous extensions of compliance deadlines, confusion in the marketplace and tremendous waste of both time and industry resources. On January 30, 2017 and February 24, 2017, President Donald Trump issued Executive Orders instructing all federal agencies to identify regulations that could be repealed, replaced or modified in accordance with the mandates of the Executive Orders. On September 8, 2017, FDA published a Request for comments entitled "Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements." 82 Fed. Reg. 42501 (published September 8, 2017) ("CTP Request"). CAA submits these comments in response to this CTP Request. As set forth below, because of the crushing financial burden it places on the cigar industry, its improper use of a regulatory "one size fits all" approach, and its failure to adequately advise what would constitute compliance, the Final Rule is precisely the type of regulation targeted by the Executive Orders.

CAA has organized its comments into the following five sections. First, background on the Executive Orders and accompanying CTP Request. Second, a brief discussion of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act").[2] Third, an outline of the Final Rule and an overview of the cigar industry. Fourth, why the Final Rule is a perfect example of a regulation to be targeted for repeal, replacement or modification. Fifth, examples of FDA's acknowledgement that it simply did not do all the work necessary to properly evaluate the Final Rule before it published it – that the agency did not "have its ducks in a row."

1. Executive Orders 13771 and 13777

Shortly after taking office, President Trump issued Executive Orders encouraging and requiring significant regulatory reform. First, on January 30, 2017, President Trump issued Executive Order 13771, entitled "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs." This Executive Order stated that "[i]t is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources."[3] The Executive Order further stated that "it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."[4] In order to fulfill this goal, it announced the so-called "one in, two out policy," that for "every one new regulation issued, at least two prior regulations be identified for elimination, and the costs of planned regulations be prudently managed and controlled through a budgeting process."[5]

Second, on February 24, 2017, President Trump further elaborated on the administration's goal of reducing the burden of regulation on American industry by issuing Executive Order 13777, entitled "Presidential Executive Order on Enforcing the Regulatory Reform Agenda." This Executive Order states "it is the policy of the United States to alleviate unnecessary regulatory

[2] Public Law 111-31, 123 Stat. 1776 (2009).

[3] Exec. Order 13,771, 82 Fed. Reg. 9339.

[4] *Id.*

[5] *Id.*

burdens placed on the American people."[6] Each agency was tasked to create a Regulatory Reform Task Force, charged with making recommendations to each Agency head regarding the "repeal, replacement or modification" of existing regulations.[7] Specifically, each Task Force is to identify regulations that

> (i) eliminate jobs, or inhibit job creation; (ii) are outdated, unnecessary, or ineffective; (iii) impose costs that exceed benefits; (iv) create serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; (v) are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or (vi) derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.[8]

This Executive Order serves as a roadmap for agencies on how to conduct the review of their existing regulations. As FDA regulates nearly "25 cents of every dollar spent by American consumers each year," it is imperative that FDA take a hard look at the financial burden of its regulations on the industries it regulates.[9]

On September 8, 2017, FDA published the CTP Request in the Federal Register. CAA submits these comments in response to FDA's request that "interested parties help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced" consistent with Executive Orders 13771 and 13777. FDA asked that interested parties address their comments within the context of certain specific questions. CAA will focus its comments on the following five questions in relation to how the Final Rule is a prime candidate for repeal, replacement or modification.

1. Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

2. Have regulated entities had difficulties complying with the regulation? If yes, what entity or entities have had such difficulties and the nature of the difficulties?

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[6] Exec. Order 13,777, 82 Fed. Reg. 12,285, sec.1.

[7] *Id.* Section 3(d).

[8] *Id.*

[9] Executive Summary: Strategic Plan for Regulatory Science. Available at: https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268095.htm (last visited November 16, 2017).

3. Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g, reporting, recordkeeping, or labeling requirements? Explain in your response why the information is redundant, outdated or unnecessary.

4. Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

5. What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

2. The Tobacco Control Act

In 1995, FDA published a Proposed Rule seeking to assert jurisdiction over tobacco products, using FDA's power to regulate medical devices.[10] FDA concluded that "cigarettes and smokeless tobacco are combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body."[11] After notice and comment, in 1996, FDA issued a Final Rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." ("1996 Final Rule")[12] This Final Rule asserted jurisdiction only over cigarettes and smokeless tobacco. In response to comments as to why FDA was only asserting jurisdiction over cigarettes and smokeless tobacco, and not all nicotine products, FDA stated the following: "there is insufficient evidence of cigar or pipe tobacco use by children and adolescents to support the inclusion of cigar, pipe tobacco" or "all presently marketed nicotine delivery devices" within the scope of the 1996 Final Rule.[13]

Cigarette and smokeless tobacco companies filed suit challenging FDA's ability to regulate these products as medical devices. The lawsuit culminated in a decision by the United States Supreme Court in 2000 which held that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products...[and] [i]n light of this clear intent, the FDA's assertion of jurisdiction is impermissible."[14]

It took Congress nearly seven years to give FDA regulatory authority over cigarettes and smokeless tobacco. The Tobacco Control Act was first introduced into Congress on February 15, 2007, and was signed into law on June 22, 2009.[15] The Tobacco Control Act immediately

[10] Regulations Restriction the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. 69 Fed. Reg. 44,396 at 44,400.

[11] *Id.*

[12] 69 Fed. Reg. 44,396.

[13] *Id.* at 44,422-23.

[14] *Food and Drug Administration, et al. v. Brown and Williamson Tobacco Corp., et al.*, 529 U.S. 120, 126 (2000).

[15] Public Law 111-31, 123 Stat. 1776 (2009).

regulated cigarettes and smokeless tobacco, roll-your-own tobacco and tobacco papers; similar to FDA in the 1996 Final Rule, Congress did not see the need to immediately regulate cigars or pipe tobacco.[16] Instead, the Tobacco Control Act only gave FDA the authority to regulate other tobacco products after "the Secretary by regulation deems [them] to be subject to this Chapter."[17]

Also similar to the 1996 Final Rule, Congress passed the Tobacco Control Act in 2009 to combat cigarette manipulation and to prevent youth from smoking cigarettes.[18] The primary focus of congressional attention was cigarettes. The *only* products that Congress mandated for immediate regulation were cigarettes, smokeless tobacco, roll-your-own tobacco, and tobacco papers.[19] Congress enacted the Tobacco Control Act against a backdrop of (i) findings that cigarette companies had manipulated ingredients in their products to make them more addictive and marketed cigarettes in a way that led consumers to believe some were safer than others[20], and (ii) a cigarette industry controlled by a handful of multi-billion-dollar companies, each of which had a few main product lines.

In the Tobacco Control Act, Congress required FDA to review and approve each "new" cigarette and smokeless tobacco product; "new" was defined as any product marketed after February 15, 2007, two years before regulation of these products started. This date was apparently chosen because, as noted above, it was the date the Tobacco Control Act was introduced in Congress, and was therefore when manufacturers of cigarettes and smokeless tobacco knew how FDA intended to regulate these products. Any product on the market prior to February 15, 2007 did not have to go through FDA's rigorous premarket approval process. Further, a new cigarette product could bypass full premarket review if the manufacturer could demonstrate that it was "substantially equivalent" to a product marketed just two years previously.

Congress made no decision whatsoever on whether cigars and pipe tobacco should be regulated at all, let alone how they should be regulated. It is clear, however, from various provisions within the Tobacco Control Act that Congress intended for all tobacco products to

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[16] *Id.*

[17] *Id.*

[18] Pub. L. 111-31, 123 Stat. 1776 (2009). The Act's explicit purposes were, among other things:
(2) to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco; [and] ...

> (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers[.]

FSPTCA § 3, 123 Stat. at 1781-82, 21 U.S.C. 387 note.

[19] The Act contains a lengthy recitation of legislative findings primarily focused on cigarettes and underage tobacco use. *See id.* § 2, 123 Stat. at 1776-81, 21 U.S.C. 387 note. Nearly half of the legislative findings (21 out of 49) address youth and adolescents, in terms of either use or marketing of tobacco. *See id.* Many others (e.g., findings 16, 38, 39, and 49) are directed specifically to the cigarette industry. *See id.* § 2(16), (38), (39), (49), 123 Stat. at 1778, 1780, 1781. The findings never mention cigars or pipe tobacco.

[20] *Id.* § 2(38)-(39), (47)-(49), 123 Stat. at 1778-81.

continue to be available to adult tobacco consumers, and to be be regulated based on their different profiles, and different industries.[21]

The Tobacco Control Act itself treats cigarettes and smokeless tobacco in different ways. Characterizing flavors other than menthol were banned in cigarettes, but not in smokeless tobacco.[22] Similarly, sampling was banned for cigarettes, but not for smokeless tobacco.[23] Further, FDA was to publish proposed rules on graphic warnings for cigarettes, but not for smokeless tobacco.[24]

In addition to these very clear specific examples, the concept that FDA is to treat products differently is infused throughout the Tobacco Control Act. For instance, any Good Manufacturing Practices "must take into account the manner in which the different types of tobacco products have historically been produced, [and] the financial resources of the different tobacco product manufacturers."[25] Tobacco Product Standards must relate to "a tobacco product" and to date (other than the ban on characterizing flavors, except menthol, in cigarettes) the only proposed standard relates to smokeless tobacco.[26] For all product standards, the Secretary is to consider "information submitted in connection with a proposed standard regarding the technical achievability of the standard."[27]

FDA itself acknowledges that not all tobacco products are the same, and that products should be regulated according to differences, including risks. In the Final Rule FDA stated that it "recognizes the existence of a continuum of nicotine delivering products and will continue to consider this continuum in regulating future tobacco products."[28] Further, FDA has recently announced a policy shift that further acknowledges this risk continuum, and that it is imperative the products are regulated appropriately on that continuum.[29]

Additionally, FDA has acknowledged there may exist a category of products entirely exempt from regulation – premium cigars. Commissioner Gottlieb stated that FDA "will explore

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[21] Two of the defined purposes of the Tobacco Control Act were to "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchases; to impose appropriate regulatory controls on the tobacco industry." *Id.* note.

[22] 21 U.S.C. §387g (a)(1).

[23] 21 U.S.C. §387a-1(d)(2)(A)-(C).

[24] 123 Stat. at 1845 sec. 201 (d).

[25] 21 U.S.C. §387f (e). In fact, on November 22, 2017, FDA announced it was opening a public dockets to take comments specifically on ENDS manufacturing practices. *See* 82 Fed. Reg. 55,613.

[26] 21 U.S.C. §387g; Proposed Rule: Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products. When FDA issues an Advanced Notice of Proposed Rule Making on the nicotine levels in combustible cigarettes, this will also be issued under Section 907. 82 Fed. Reg. 8004.

[27] 21 U.S.C. §387g (b)(1).

[28] 81 Fed. Reg. 29,050.

[29] Protecting American Families: Comprehensive Approach to Nicotine and Tobacco. Remarks by Scott Gottlieb, M.D., July 28, 2017. Available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last visited November 16, 2017).

any new and different questions raised, and seriously consider any additional data submitted relevant to the appropriate regulatory status of premium cigars."[30] While the actual Advance Notice of Proposed Rulemaking on this issue has yet to be published, the Abstract for it states that FDA is looking at "exempting these products from regulation or regulating them in a different manner from other cigars."[31] This is a clear additional acknowledgement that Congress intended, and FDA at times recognizes, that its mandate is to regulate product by product, and not use the "one size fits all approach" in the Final Rule.

3. The Final Rule

(a) The Rule Making Process

On April 25, 2014, nearly five years after the passage of the Tobacco Control Act, FDA issued a Proposed Rule to deem all tobacco products subject to its authority.[32] With respect to cigars, the Proposed Deeming Rule had two options. The first would deem all cigars to be subject to FDA's jurisdiction. The second, known as "Option Two," would exempt premium cigars from regulation.[33] CAA submitted comments to the Proposed Deeming Rule and supported FDA's proposed Option Two, and suggested an alternative regulatory path should FDA adopt Option One.[34]

On May 10, 2016, FDA issued the Final Rule – rejecting Option Two, and ignoring the comments of CAA, other industry trade associations and cigar companies, and treating all cigars in the exact same way.[35] The Final Rule takes the entire regulatory scheme developed by Congress and implemented by FDA for cigarettes – and imposes it wholesale on cigars. It requires manufacturers, regardless of their size or the nature of the products they offer, to file laborious premarket applications, accompanied by hugely expensive product testing and detailed scientific data.[36] To make matters worse, in order for cigars to take advantage of the same substantial equivalence pathway cigarettes used, they must compare all products they introduced into commerce between February 15, 2007 and August 8, 2016 to products that were marketed prior to

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[30] *Id.*

[31] Regulatory Information Abstract "Premium Cigars; Request for Scientific Information" available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AH88 (last visited January 22, 2018).

[32] Deeming Tobacco Products to be Subject to the Food, Drug and Cosmetic Act, as Amended by the Family Smoking and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements. ("Proposed Deeming Rule") 79 Fed. Reg. 23,142.

[33] 79 Fed. Reg. 23,150.

[34] Cigar Association of America, Inc. Comment Letter to Proposed Deeming Rule filed on August 7, 2014 ("CAA Comment).

[35] 81 Fed. Reg. 28,974.

[36] The only concession made for "small tobacco product manufacturers" (defined as having less than 150 employees and less than $5 million in revenue) was that they could have extra time to comply with the requirements of the Final Rule, not that there could be any less onerous pathway for them for any of the requirements of the Final Rule.

February 15, 2007. This nine-year "look back" period is four and a half times the two year period applicable to cigarettes - the products Congress determined needed to be immediately subject to regulation due to their placement on the continuum of risk.

(b) The Cigar Industry

FDA adopted this "one size fits all" approach notwithstanding the fact that the cigar industry is a fraction of the size of the cigarette industry, and the premium cigar industry is roughly 0.01% of the entire tobacco industry.[37] These percentages do not even account for the smaller percentage these industries occupy now that e-cigarettes have entered the marketplace. These numbers are likely to decrease as the e-cigarette category continues to grow and take over a larger percentage of the tobacco space. One recent study stated that e-cigarette sales have increased by 150% from 2012-2013 alone.[38] It is estimated that the e-cigarette industry will exhibit growth of 22.36% from 2015 until 2025 to reach a total market value of $50 billion.[39] The market position of cigars will only decline with this rapid increase in sales of e-cigarettes.

The difference in the number of products in these categories is also striking. There are only a few main brands of cigarettes on the market, and most likely only about 100 products. The cigar industry, however, and the premium cigar industry in particular, is incredibly different.

Cigars are an entirely different product from cigarettes. Cigars use different tobaccos, different methods of production, different advertising and marketing, different modes of retail sale, and have different customer demographics. Further, as FDA itself has noted, cigars themselves are not a uniform product, and have differences between and among products. It is therefore inappropriate and violates sound regulatory policy to regulate cigars according to the "one size fits all" approach.

The Final Rule defines a "cigar" as a product that "(1) is not a cigarette; and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco."[40] For tax purposes, the IRS groups cigars into two different categories: small and large.[41] In the large cigar category there is great variability including cigars with different shapes, sizes and types of construction. All cigars are constructed of wrappers, binders and fillers – the differences arise due the variety of these elements in each cigar. These three components are predominately, and at times, exclusively, tobacco, and therefore cigars are much more dependent on the agricultural product of tobacco than

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[37] Tobacco Product User Fee Assessment Formulation by Product Class. Available at https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/manufacturing/ucm521052.htm (last visited November 22, 2017).

[38] *See* Marynak et al. National and State Trends in Sales of Cigarettes and E-Cigarettes, U.S., 2011-2015. Am. J. Prev. Med. 2017 July; 53(1):96-101/

[39] *See* BIS Research Report, Electronic Cigarettes and E-Vapor Market Research Reports, 2016.

[40] 21 C.F.R, §1143.1.

[41] Small cigars weigh "not more than 3 pounds per thousand" and large cigars weigh "more than 3 pounds per thousand" 26 U.S.C. § 5702(a)(1)-(2).

cigarettes or other segments of the tobacco industry. FDA has acknowledged that cigars are more dependent on the natural variations of tobacco in recognizing that it "does not intend to enforce the premarket review requirements against cigar manufacturers that make tobacco blending changes to address the natural variation of tobacco (*e.g.* tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product."[42]

Further, unlike cigarettes, cigars are not uniformly manufactured and packaged. Cigarettes are manufactured by machines that can produce nearly 1,000,000 cigarettes in an hour, and are sold in the United States only in packs of at least 20. The major difference in packaging for cigarettes is whether they come in a "hard pack" or "soft pack." This is not the case for cigars. Cigars can be manufactured by machine, by a combination of machine and hand rolling, or entirely by hand. For cigars made by hand, one CAA member company has reported that a team making these premium cigar cannot make more than 25 cigars per hour, and the process can have over 300 manual steps.[43] Each brand can have a variety of size and shapes within it, and each brand can be sold in different product quantities and package types. Cigars can be sold individually and can be packaged many different ways, including in cellophane, plastic packages, ceramic jars, cardboard cartons or wooden boxes. In addition, while virtually all cigarettes sold in the United States are the same size, cigar size varies dramatically: the smallest cigar may weigh under 3 pounds per thousand while the largest may weigh 10 pounds per thousand (or more). Moreover, while cigarettes are all shaped in the same, cigars come in over a dozen different shapes.

Finally, the consumer base for the cigarette and cigar industries is different, and each seeks different things in its products. Cigarette consumers are brand loyal and are looking for a consistent product upon every purchase of a specific cigarette brand. On the other hand, cigar consumers frequently purchase more than one brand or sub-brand at a time, for different taste reasons and different occasions, necessitating the product variety offered by cigar manufacturers.

FDA simply ignored these dramatic differences in imposing a cigarette regulatory structure on cigars. FDA took its "one size fits all" approach, which is appropriate for a "one size" product, and imposed it on a product that is the exact opposite – a product with varied manufacturing practices, a diverse product offering and a different consumer base.

(c) Major Provisions of the Final Rule

While there are numerous provisions in the Final Rule that are burdensome to cigar companies, the following are of particular concern. Each separately violates the mandates behind the Executive Orders; taken together, they compel the conclusion that the Final Rule cannot – as written – be applied to cigars.

(i) Health Warnings

The Final Rule requires that cigar packages and advertisements carry six rotating warnings that cover 30% of the *two* principal display panels of packages and the top 20% of advertisements.

[42] 81 Fed. Reg. at 29,026.

[43] AUSA PCD Comment Letter to Proposed Deeming Rule filed on August 6, 2014 ("AUSA PCD Comment") at 7.

Companies must submit a Cigar Warning Rotation Plan twelve months in advance of marketing or advertising *any* new brand of cigars and have that Cigar Warning Rotation Plan approved by FDA prior to introducing the brand into commerce or advertising it. This requirement also includes retailers that direct any advertising for the brands they sell – they must also submit a Cigar Warning Rotation Plan, even when they do not own the trademarks of the products advertised. The seven largest cigar manufacturers have been putting five rotating warnings on their cigar packages and advertisements since signing the FTC Consent Decree in 2001.[44] (*See* Section 4(a)(ii) below) The FTC Consent Decree based the sizes of the warnings on the surface area of each package and advertisement, therefore package warnings are produced in a limited number of sizes.

(ii) HPHC Testing

The Final Rule states that all newly deemed tobacco products must comply with the requirement to report test results of Harmful and Potentially Harmful Chemicals ("HPHCs") in the products by 2019. No Guidance has been offered by FDA, however, as to how to test the newly deemed products, or what HPHCs will have to be tested for. Moreover, HPHC testing for cigars would be prohibitively expensive.[45]

(iii) Premarket Review

As noted above, The Tobacco Control Act requires a system of premarket review for all tobacco products, however, it is up to FDA to implement that system. In the Final Rule, FDA took the exact same parameters it had been using for cigarettes and smokeless tobacco and grafted them onto the newly deemed products. Due to the FDA deeming cigars later, there is, however, one very large exception to this. The predicate date for cigarettes was February 15, 2007. Therefore, at the time of initial regulation "new" cigarettes only had to look back two years for a predicate product in order to make a showing of substantial equivalence. For cigars, however, because FDA maintained it could not change the predicate date, there is no equal playing field.[46] Instead of only having to look back a few years for a predicate product for substantial equivalence, cigars will now have to potentially look back over a decade in some circumstances for predicate products.

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

[45] CAA member companies have received quotations from laboratories that can *try* to test cigars (as there is no established methodology for testing large or premium cigars). Depending on the number of HPHCs to be tested and the scope of the testing, the costs range from $5000 to $20,000 per product.

[46] "FDA concludes that it lacks authority to change the grandfather date for the newly deemed products. The grandfather date is prescribed in the statute. Section 910(a)(1)(A) of the FD&C Act states, in pertinent part, that the term "new tobacco product" means any tobacco product (including those products in test markets) that was not commercially marketed in the United States on February 15, 2007. For purposes of the SE pathway, the statute also clearly states that a predicate product must be commercially marketed (other than for test marketing) in the United States on February 15, 2007, in both section 910(a)(2)(A) and section 910(j)(1). FDA's authority is not so broad as to allow FDA to issue a regulation that contradicts a clear statutory provision." 81 Fed. Reg. at 28,993. Yet, FDA has indicated its authority is broad enough to use enforcement discretion through a Draft Guidance document to not enforce the statutory provision in Section 903(a)(2)(c). *See infra*, note 96.

Additionally, FDA has to date provided no guidance on any product specific requirements for what cigar substantial equivalence applications would need to contain.

4. The Final Rule is Appropriate for Repeal, Replacement or Modification

(a) Considerations Under Executive Order 13777

As noted above, Executive Order 13777 requires each agency to identify regulations that violate principles of sound regulatory policy. The Final Rule clearly violates most of them, and is a perfect example of a regulation that merits repeal, replacement or modification.

(i) Does the Rule Eliminate Jobs or Inhibit Job Creation

The cigar industry sells its products to adult consumers who often appreciate variety, seeking new and different cigars. Unlike the cigarette industry, where brand loyalty results in large market leaders and only a few well-known brands of cigarettes, the cigar industry is known for a plethora of brands made by a large number of manufacturers.

Since FDA published the Final Rule, there has already begun to be consolidation in the cigar space.[47] Smaller companies simply cannot handle the crushing costs associated with FDA requirements.[48] As noted above, for cigar products, FDA assumed that all "new" products would file substantial equivalence reports based on a 2007 product. Some cigar companies, however, were not even in business in 2007, so by definition cannot have a predicate product they can compare to for a substantial equivalence application. In the context of an SE Product Quantity Change Application, FDA has stated that "[w]e expect the manufacturer of the new product will generally be the same as the manufacturer of the predicate product."[49] While theoretically possible for FDA to consider an SE Report where the predicate product was manufactured by a company that did not also manufacture the new product, such an approach raises practical problems. For example, many companies, including some CAA member companies, will be forced to either come to commercial arrangements to rely on the predicate products of other companies, with no true knowledge of whether those products are substantially equivalent to the new cigars, or will be forced to go through the even more prohibitively expensive pre-market tobacco product

[47] Baracoa Cigar Co. Shuts Down, Cites FDA. Available at http://halfwheel.com/baracoa-cigar-co-shuts-cites-fda/169947 (last visited November 16, 2017); Patrick Vivalo Shuts Down Vivalo Cigars, Joins La Palina. Available at http://halfwheel.com/patrick-vivalo-joins-la-palina-shuts-down-vivalo-cigars/108410 (last visited November 16, 2017); Edolara Cigars Shutting Down. Available at http://halfwheel.com/eduardo-de-lara-of-edolara-cigars-leaving-cigar-industry/132584 (last visited November 16, 2017); Dominican cigar makers turn to Europe, China for market. Available at https://www.fredericknewspost.com/news/economy_and_business/dominican-cigar-makers-turn-to-europe-china-for-market/article_d3afe5a0-3a5b-52a9-a9b2-1d397b8ee81f.html (last visited January 29, 2018).

[48] This of course, while the e-cigarette market continues to grow exponentially. The e-cigarette market continues to grow, and does so, without having to pay to fund CTP through user fees as the cigar industry does.

[49] Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3), December 2016 at 8 ("SE Report FAQ Guidance").

application ("PMTA") pathway.[50] There is actually no choice – these companies will have to close their doors before undergoing the even more rigorous PMTA pathway.

Even for companies with many predicate products, the challenge of recreating those products and submitting a substantial equivalence report for every single cigar introduced since 2007 will be crushing. Additionally, FDA requires a substantial equivalence report for every product quantity change.[51] So if a cigar was originally launched in a box of 20, and then is released later (post-2007) in a box of 10, it will need to have a Product Quantity Change SE Report filed for it. Many companies have already begun plans to rationalize their portfolios. Eventually, fewer products on the market, and fewer products coming to market, will mean fewer jobs. It is plain that these regulations will inhibit job creation at cigar manufacturing, distributing and retail companies.

CAA is particularly concerned about the effect of the Final Rule on the remaining jobs in the domestic cigar manufacturing industry. The cigar industry has a long history in the United States, and especially in Florida. In times past many cigar manufacturers called Tampa home – today only one company employing approximately 100 people remains. At least one cigar manufacturer resides in cities such as Miami; Union City; Las Vegas; Los Angeles; Dothan, Alabama, and Jacksonville, with the Jacksonville facility employing approximately 400 manufacturing personnel.[52] The crushing burden of FDA regulation could force these domestic manufacturers to reduce their workforce or close their doors entirely.[53]

(ii) Does the Rule Impose Costs that Exceed Benefits

Executive Orders 13771 and 13777 carry through the principles of sound regulatory policy that have been reiterated by administration after administration – that "each agency shall assess both the costs and the benefits of the intended regulation and...adopt a regulation only upon a

[50] There is a possibility that a manufacturer could rely on a Tobacco Product Master File of filed by another manufacturer for a predicate product. However, the Draft Guidance provided on Tobacco Product Master Files is incredibly slim, and does not seem to contemplate the contents being used as the basis for an SE Report, but instead only for parts of products ("including but not limited to materials, parts, components and accessories of tobacco products, or the facilities, processes or articles use in the manufacturing, processing, packaging and storing of tobacco products.") Draft Guidance for Industry: Tobacco Product Master Files, May 2016. Also, this would not allow the manufacturer of the new tobacco product to reliably complete an SE Report showing the comparisons between the predicate and new tobacco products.

[51] In determining that a change to the product quantity requires a substantial equivalence report, FDA created a new pathway, not outlined in the Tobacco Control Act, so that companies could file "streamlined" Product Quantity Change SE Applications for these products. However, even this "streamlined" SE Report,requires "scientific data demonstrating that the new change in product quantity is not likely to alter consumer use behavior of the new product compared to the predicate product." SE Report FAQ Guidance. at 9.

[52] CAA Comment at 36.

[53] CAA is also concerned about the thousands of jobs outside of the United States that the Final Rule affects. The cigar industry employs thousands of people in countries such as the Dominican Republic, Honduras and Nicaragua and the crushing burdens of the Final Rule places these jobs in jeopardy as well.

reasoned determination that the benefits of the intended regulation justify its costs."[54] The Tobacco Control Act states that one of its ten purposes is to "impose *appropriate* regulatory controls on the tobacco industry."[55] The definition of "appropriate" is "especially suitable or comparable."[56] The Final Rule states "[t]he direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify and we cannot predict the benefits at this time."[57] CAA member companies can estimate many of the near and future costs the regulation is imposing on their businesses (despite FDA's alarming lack of specificity or care in that regard); even though FDA admits it cannot "predict the benefits" of the regulation in relation to any of the newly deemed products.

These comments outline numerous provisions of the Final Rule where the costs of the Final Rule exceed benefits, and could be repealed, replaced or modified in order to be consistent with sound regulatory policy. In order to evaluate the total cost of the Final Rule, CAA attaches a report prepared by Policy Navigation Group that analyzes FDA's cost benefit analysis in more exacting detail.[58] Specifically, the report details FDA's

- failure to quantify how the post-regulation cigar market will be impacted by product withdrawals and likely consumer surplus loss;
- mind-boggling assumption that HPHC testing will carry no cost to industry; and
- demonstrably incorrect assumptions and erroneous calculations contained in its cost estimates for substantial equivalence reports.

[54] Exec. Order No. 12,866, 58 Fed. Reg. 735 (Oct. 4, 1993).

[55] 123 Stat. 1777, 1783, sec. 3 (8) (emphasis added).

[56] https://www.merriam-webster.com/dictionary/appropriate

[57] 81 Fed. Reg. at 29,075 (emphasis added).

[58] Policy Navigation Group is a diverse team of senior policy analysts with OMB experience, managers, economists, engineers, lawyers and skilled researchers. The team is lead by President Jonathan Gledhill. Mr. Gledhill has advised trade associations and Fortune 100 clients on regulatory policy issues for over ten years. Prior to founding Policy Navigation Group, Mr. Gledhill worked at The EOP Group in Washington, DC. Prior to The EOP Group, Mr. Gledhill worked in the Natural Resources Branch of the White House Office of Management and Budget (OMB) for over four years reviewing regulatory, policy, and economic issues. Mr. Gledhill was the primary analyst for all hazardous and solid waste regulations and policies for OMB. Other issue areas included Superfund, the Emergency Planning and Community Right to Know Act, Safe Drinking Water Act, housing standards, and underground injection regulation. Mr. Gledhill was recognized and awarded for outstanding professional achievement each year of his employment at OMB. Mr. Gledhill received a Master in Public Policy degree from the John F. Kennedy School of Government at Harvard University with concentrations in science and public policy and the environment and public policy. Mr. Gledhill graduated magna cum laude from Princeton University with a Bachelor of Science of Engineering degree in Civil Engineering. Mr. Gledhill also worked as an environmental engineer designing and operating drinking water and water treatment facilities.

The report also contains a proper analysis of market adjustment, lost consumer surplus and the overall economic impact of the Final Rule.[59]

The Final Rule violates sound regulatory policy in a number of ways. First, FDA drastically underestimated the number of products that the Final Rule would cover. FDA estimated a baseline of 7,500 cigar products subject to the rule, 4,500 of which it predicted would be grandfathered and 2,625 of which would be submitted for premarket review and 375 (or 5%) would exit the market.[60] In 2014, cigar companies and trade associations told FDA there were many thousands of cigar products on the market.[61] These comments illustrate how vastly inaccurate FDA's estimate was.[62] By severely underestimating the volume of products in the industry, it also means that any cost estimates FDA presented were woefully inadequate.

Second, the Final Rule requires any company that "repackages" or "relabels" a tobacco product to register as a manufacturer and comply with nearly all of the requirements of a tobacco product manufacturer.[63] This requirement turns hundreds of small retail tobacconists, as well as some of the largest cigar retailers, into manufacturers. Cigar retailers routinely make cigar samplers – a combination of cigars of different brands sold together – to satisfy consumer demand to try new products without having to buy an entire box of each cigar. Similarly, cigar retailers often sell cigars in smaller package quantities then what the manufacturer sells, so again rather than buying 20 of one cigar, a consumer could purchase 4 different "5-packs" to have a variety of products. FDA has determined this activity is "manufacturing" and that each sampler and 5-pack is a "new tobacco product." Additionally, FDA has determined that blending pipe tobacco – the action of a retail tobacconist mixing two finished blends together to create a new one – is "manufacturing" activity and that these tobacconists are now manufacturers. Finally, retail tobacconists also often buy pipe tobacco in bulk and then sell this bulk in smaller quantities. Just as in the cigar context, FDA considers this "manufacturing" activity. All FDA said in response to the concerns over what imposing these onerous regulations on retailers who are simply conducting business as they always have done was "[r]etailers who currently meet the definition of manufacturer may continue to operate but cease to engage in manufacturing activities and convert

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[59] *See* Exhibit A "Evaluation of the Burden Reduction Opportunities in the Food and Drug Administration's Final Rule: Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act" Submitted by Policy Navigation Group, January 2018.

[60] Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Regulatory Impact Analysis, May 2016 at 84 ("FRIA").

[61] CAA Comment at 6; AUSA PCD Comment at 5; General Cigar Company Comment to Proposed Deeming Rule filed on August 7, 2014 (General Cigar Comment) at 3.

[62] There was no reason for FDA's estimate to be so inaccurate. Many cigar companies put in comments to the Proposed Deeming Rule stating how many products they had. For example, In 2014, Altadis, USA, Inc. Premium Cigar Division had 1566 SKUs. AUSA PCD Comment at 5. Davidoff of Geneva USA stated they had 1670 SKUs. Davidoff of Geneva USA, Inc. Comment at 6. Additionally, J.C. Newman stated it sold 833 SKUs in 2014. J.C. Newman Cigar Company Comment at 16.

[63] 81 Fed. Reg. at 29,049-50.

to a pure retail model."[64] Such dismissive comments show utter disregard for the hundreds or thousands of small businesses forced to live under FDA authority.

CAA member companies meeting the definition of "manufacturer" have spent hundreds of hours completing the registration and listing and ingredient reporting required for every product sold. This requires methodical work to upload pictures of all labeling for every product, as well as to work with FDA's computer systems, which have been subpar at best.[65] Ingredient reporting has required meticulous preparation to find and verify the data, and again input it into software that has constant technical problems. FDA finally recognized the overwhelming burden on industry, and once again that the software it forces industry to use was malfunctioning, and extended the ingredient listing deadline by six months – it did this roughly 33 hours before the final deadline.[66]

Third, CAA member companies will be required to comply with the new FDA health warning requirements. Most of the cigar industry has had rotating health warnings on all cigars since 2001. These warnings are nearly identical in substance to the new FDA warnings.[67] Under the FTC Consent Decree, however, packages carry one warning that is tailored to the size of the box, needing to be "clear and conspicuous." FDA never explained in the Final Rule why the FTC Consent Decree warnings were no longer adequate to warn the public of the dangers of cigar smoke. FDA agreed that the content was acceptable, as the agency adopted nearly the same warnings. Without explanation, however, FDA mandated much larger warnings, covering 30% of the two principal display panels of every package. As the packaging for cigars is often artistic and comes in a variety of shapes and sizes, a huge effort will have to be made to redesign all packaging and labeling to accommodate the warnings. Further, as cigar packaging is not a uniform size, unlike a pack of cigarettes, the warning labels will have to be printed in hundreds of different sizes to accommodate the different packaging sizes and options offered by CAA member companies.[68]

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[64] FRIA at 104.

[65] In fact, there have been so many technology problems that FDA extended the registration and product listing deadline solely due to the poor performance of its software. ("Due to intermittent outages of the FDA Unified Registration and Listing System (FURLS), the FDA has extended the registration and listing compliance deadline until October 12, 2017.")
https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm386651.htm (last visited November 16, 2017).

[66] An email from FDA to stakeholders was sent at 2:27 p.m. on Tuesday, November 7, 2017 with the deadline originally being Wednesday November 8, 2017. The email stated that "FDA is extending the compliance deadline to submit ingredient listings for deemed tobacco products by six months due to technical issues users encountered with eSubmitter." However, with only 33 hours left before the deadline this delay did little to alleviate the required effort and cost already incurred by many CAA member companies.

[67] FDA did make one change to remove the so-called "reproductive harm" warning and replaced it with "WARNING: Cigar use while pregnant can harm you and your baby." However, FDA stated that entities bound by the FTC Consent decree could continue to use the so-called "reproductive harm" warning. 81 Fed. Reg. 29,071. FDA also added the following sixth warning "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 81 Fed. Reg. 29,061.

[68] *See* Declaration of Rob Norris, General Manager of Altadis U.S.A., Inc. Filed in *Cigar Association of America et al. v. United States Food and Drug Administration, et al.*. Docket No. 16-1460 District of Columbia.

One CAA member company has estimated that it will cost nearly $1.3 million dollars to change packaging, order new warnings, retire old packaging, and other issues just to get the new FDA warnings into production.[69] This same company then estimates an ongoing additional annual expense of approximately $250,000 relating to the warning labels.[70] All of these costs are being incurred by CAA member companies against the backdrop of FDA stating "[r]eliable evidence on the impacts of warning labels on users of cigars...does not, to our knowledge, exist."[71] This has been done, again, without an estimate of the benefits to the public health. Indeed, FDA acknowledges it cannot estimate the benefits.[72]

Fourth, according to the provisions of the Final Rule all cigars will have to undergo HPHC testing and report the results to FDA. This requirement violates the principles of sound regulation in a few ways, and poses significant problems for many cigars. First, FDA has not yet established a required list of HPHCs for testing in cigars. Second, unlike for cigarettes, there is no standard methodology or smoking machine available to test cigars. For cigarettes, there are two well-developed protocols (the ISO regime and the Canadian Intense regime) for testing cigarette smoke. In addition, because cigarettes are a standard size and shape there are well developed testing machines and reference cigarette products.

This is not the same for cigars at all. Cigars come in many sizes and shapes, many of which cannot fit in any standard smoking machine. Further, while there have been methodologies created for certain cigars, these smoke testing methodologies are not capable of being reliably used to test for all cigars, especially for large, handmade cigars. Currently, the cost estimates for performing HPHC testing range from $5000-$20,000 per sku depending on the testing required. For a standard product such as cigarettes, that is available in only a few brands, this testing may have benefits that exceed the costs. For cigars, however, FDA has not articulated any benefits that exceed these vast costs.[73] All FDA says in justification is "we cannot quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects."[74] What is certain, however, are the huge costs CAA member companies will have to incur to comply with the Final Rule.

Sixth, while the above examples are dramatic, the most severe violation of the cost/benefit principle is in the area of premarket review. As previously discussed, every product introduced to the market after February 15, 2007 will have to undergo premarket review to continue to be sold

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[69] *Id.*

[70] *Id.*

[71] FRIA at 62.

[72] *Id.*

[73] A specific way that the Final Rule could be modified to both assist industry and give FDA more accurate and reliable testing would be to eliminate the standalone HPHC testing requirement for cigars and pipe tobacco, and instead incorporate these requirements into premarket review. This would allow for an additional two years of research into appropriate testing methodologies for these products, and allow industry to provide FDA with more reliable and appropriate data.

[74] FRIA at 67.

after August 8, 2021. FDA estimated that it would take 220 hours to complete a full initial Substantial Equivalence Report ("SE Report"), as well as 80 hours to complete the accompanying environmental assessment.[75] FDA then valued this at $22,787 per initial SE Report.[76]

Once again, FDA's estimates are woefully deficient. If FDA were to adopt reasonable requirements for the form and content of cigar SE Reports, then this number might be realistic. It currently seems, however, that FDA is on track to request testing results of both the tobacco and the smoke for both the predicate and the new cigar. The testing costs alone will be over $22,000 per application. CAA member companies estimate that each SE Report may cost a minimum of $250,000. In justifying the benefits of premarket review FDA stated that "[t]he requirement of premarket review leads to fewer harmful or addictive products reaching the market."[77] It is clear the goal of these provisions of the Final Rule is reduce the number of cigars coming to market- not because they are "harmful" but simply because they are "new." Further, as it currently stands, it appears FDA will require every cigar sampler or retailer created "5-pack" introduced since 2007 to undergo premarket review. First, how this will even be feasible when the retailer manufacturers will not have the information for these products is an outstanding question. Second, FDA has not articulated what public health benefit exists to this review of products that will already be subject to premarket review through the applications that must be filed by the actual manufacturers of the products.

The costs of the Final Rule far exceed any of the unquantified and unstated benefits, and violate principles of sound regulatory policy.

(b) Questions to be Addressed

The CTP Request provided a number of specific questions interested parties are requested to consider in their comments as to why an identified regulation is a candidate for repeal, replacement or modification. CAA will address questions 2, 5, 10, 12, and 13 with respect to why the Final Rule should be repealed, replaced or modified.

(i) Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

As discussed above, FDA first attempted to regulate tobacco products in 1995. The 1995 Proposed Rule said the following in relation to its decision not to propose to regulate cigars:

> The proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act. FDA has focused its

[75] *Id.* at 93.

[76] *Id.* at 94. FDA further stated that "the costs of undergoing premarket review are expected to be relatively low for cigar products that seek marketing authorization through the substantial equivalence or substantial equivalence exemption pathways." *Id.* at 75.

[77] *Id.* at 65.

> investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products.[78]

The 1996 Final Rule stated the following in relation to the final decision to not regulate cigars:

> The agency advises that, at this time, there is insufficient evidence of cigar or pipe tobacco use by children and adolescents to support the inclusion of cigars, pipe tobacco, or ''all presently marketed nicotine delivery devices'' within the scope of the final rule.[79]

In 1998, the National Cancer Institute published what is still the only government Monograph on cigars.[80] This Monograph stated that "as many as three-quarters of premium cigar smokers smoke only occasionally, and some may only smoke a few cigars per year."[81] More recently, in 2013 a CAA member company did a survey of approximately 1,000 premium cigar smokers found that approximately 48% smoked fewer than seven cigars per month, and a majority smoked 2 to 3 cigars per week.[82]

In 2009, the Tobacco Control Act did not include cigars in the categories of products for initial regulation by FDA. Since there is no mention of cigars in the legislative history of the Act, one can only assume that it did not include this category because the science and data relating to cigars as a "nicotine delivery device" and youth usage of cigars had not changed, and therefore did not warrant Congressional action.

Youth usage of tobacco products is a widely tracked and surveyed area, and was one of great concern to FDA in deciding to regulate cigars. While youth usage of tobacco products is an incredibly important issue, the concerns are not the same regarding youth usage of cigars as with cigarettes. In fact, youth usage of cigars has declined since both FDA's original attempt to regulate some tobacco products via the 1996 Final Rule (which excluded cigars, as noted above) and since enactment of the Tobacco Control Act (which similarly excluded cigars).

One of the most long-standing and well-respected surveys of youth usage is the National Survey on Drug Use and Health ("NSDUH"). The NSDUH survey results show that youth usage of cigars actually declined between 1997 and 2009. In 1997, the NSDUH survey showed that only

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[78] 60 Fed. Reg. at 41,322.

[79] 61 Fed Red. at 44,322-23.

[80] NATIONAL CANCER INSTITUTE, CIGARS: SMOKING AND TOBACCO CONTROL MONOGRAPH 9: CIGARS, HEALTH EFFECTS AND Trends (1998).

[81] *Id.* at preamble.

[82] AUSA PCD comment at 15.

5.0% of 12-17 year olds reported using cigar products in the past month, where as in 2009, 4.0% of youth aged 12-17 reported using cigar products in the past month.[83]

More recent data shows a continuation of the downward trend. The Proposed Deeming Rule was published in 2014, when the NSDUH data showed that only 2.1% of youth aged 12-17 reported using a cigar product in the past month.[84] In 2016, the year FDA issued the Final Rule, this number had fallen to 1.8% of youth aged 12-17, yet the cigarette use number was at 7.2%.[85] Other data regarding the overall decline of youth usage of cigars is similarly compelling. FDA has funded a study entitled the Population Assessment of Tobacco and Health ("PATH") study which is a nationally, representative longitudinal study of tobacco use and health in the United States. The first Wave of data from the PATH study has begun to be reported. A recent study analyzing this data reported that only 2.5% of youths reported previous 30 day cigar use.[86] Of this 2.5%, only 0.7% reported using "traditional cigars."[87] In contrast, the study reported that 4.6% of youth used cigarettes in the past 30 days.[88]

The above demonstrates that the *lack* of change in the science (i.e., that youth usage has not increased), as opposed to advancement in science, supports repeal, replacement or modification of the Final Rule. The FDA's initial decision in 1995 that "young people predominantly use cigarettes and smokeless tobacco" holds true, and is even further supported by, data available today. Moreover, there is little support available that youth usage concerns warrant the depth and breadth of regulation of cigars provided for in the Final Rule.

(ii) Have regulated entities had difficulties complying with the regulation? If yes, what entity or entities have had such difficulties and the nature of the difficulties?

CAA member companies have already had difficulty in complying with the Final Rule, and anticipate having problems with future compliance responsibilities due to the crushing costs and lack of guidance from FDA.

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[83] 1997 was the first year the NSDUH survey included data on tobacco use. 1997 NSDUH Survey Results available at http://datafiles.samhsa.gov/study/national-household-survey-drug-abuse-nhsda-1997-nid13619 (last visited November 16, 2017). 2009 NSDUH Survey Results are available at http://datafiles.samhsa.gov/study/national-survey-drug-use-and-health-nsduh-2009-nid13531 (last visited November 16, 2017).

[84] NSDUH 2014 Survey Results, Table 2.33B available at https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf (last visited November 16, 2017).

[85] NSDUH 2016 Survey Results, Table 2.45B; Table 2.40B. https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.htm#tab2-44B (last visited November 16, 2017).

[86] Kasza et al. Tobacco-Product Use by Adults and Youth in the United States in 2013 and 2014. N Engl J Med. 2017; 376:342-353.

[87] "Traditional cigars" was defined as "traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta and Arturo Fuente, but there are many others."; Kansza Supplementary Appendix, Table S18.

[88] *Id.*

CAA member companies have had an incredibly difficult time complying with the Establishment Registration and Product Listing compliance requirements. These problems were mostly due to the FURLS (FDA Unified Registration and Listing System) system required to be used by FDA. The FURLS system has routinely frozen, deleted products entered, been unavailable, and had other issues over the course of the year. Additionally, FDA made large updates to the system in February 2017 which caused companies to have to redo work. CAA member companies have had to routinely work with the FDA helpdesk to resolve these problems. In fact, as noted earlier, FDA had to extend the compliance deadline multiple times due to the problems with the FURLS system.

The Final Rule also requires that companies submit ingredient listings for their products. For a standard, machine made product such as a cigarette, this makes sense, and the forms FDA has created make sense for the ingredients for that product. For cigars, a product that is generally made from natural tobacco leaves through different manufacturing processes, the ingredient reporting process both does not make sense and makes compliance challenging. For cigar samplers, where the ingredients themselves are other finished tobacco products, the process was simply illogical. FDA did not tailor the ingredient reporting forms to the newly deemed products, resulting in every product using the form created for cigarettes. Additionally, there has been little support from the agency. With other compliance requirements, FDA has created a specific email address for industry to use to ask questions, such as CTPRegistrationandListing@fda.hhs.gov. However, no such email address was ever announced for ingredient reporting, leaving companies to guess at their compliance obligations when the "basic instructions", again written for cigarettes, did not make sense in terms of cigars. As discussed above, once again, on the eve of a deadline, FDA finally acknowledged the problems with the eSubmitter system (but not the ingredient reporting set-up itself) and extended the compliance deadline by six months.[89]

CAA anticipates that its member companies will continue to have problems complying with the requirements of the Final Rule from many different perspectives. First, the upcoming compliance deadlines relating to health warnings and premarket review are crushingly expensive. As discussed above in Section 4(a)(ii), one member company will have to spend approximately $1.3 million just to become compliant with the new health warning label requirements, and then expects to spend an additional $250,000 annually to continue to comply. Additionally, there are only a few companies that can make these health warning labels.

CAA member companies will also have to redesign and recreate all of their advertising and point of sale materials. Further, while FDA has refused to define advertising in the Final Rule, it has stated it is to be "interpreted broadly."[90] Included within this "broad interpretation" are new and unique media where a top 20% warning simply is not logical or achievable. FDA has stated it will provide Guidance for warnings on these "unique" media, but to date none has been forth-coming.[91] CAA member companies will be required to comply with guidelines in less than a year that FDA has yet to issue.

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[89] *See* supra note 66.

[90] 81 Fed. Reg. at 29,062.

[91] *Id.*

The problem is even more glaring in relation to pre-market review and cigar testing. Here the costs are staggering, and at this point must be expended without Guidance from FDA. FDA has yet to provide guidance as to what will be required to make a substantial equivalence determination for cigars, so companies are left to prepare in a vacuum.[92] Regarding HPHC testing, again FDA has yet to release a list of required HPHC's for cigars. However, even once this list is released, there are still significant hurdles to compliance in addition to cost. For certain cigars there is no established testing methodology, nor are there smoking machines that can accommodate the different shapes and sizes of premium cigars. Further, even if these issues are resolved, there is limited lab space available for testing. There is a real possibility that due to the methodology issues and lack of lab space that certain cigar companies will not be able to comply with HPHC testing by the current compliance deadline.

Finally, all of the FDA compliance requirements were written originally for a standard, machine generated product with many additives and specifications. Cigars are generally different from this. They are not standard, are made through a variety of manufacturing processes and only occasionally have additives. Each cigar is dependent on the tobaccos available and the growth conditions of that tobacco. For instance, cigarette production will not be effected by climate and weather issues as the product is so standard. Cigars, however, are dependent on climate conditions for the tobacco grown each year for the products. Further, while nearly all cigarettes commercially marketed in the United States are manufactured here, using tobacco grown here, such is not the case for cigars. The large majority of cigars sold in the United States are imported from other countries, and even those manufactured in the United States generally use foreign tobaccos. Due to this international factor, as happened this year, cigar production and distribution can be effected by hurricanes and other natural disasters.[93] All of these issues will continue to impact CAA member companies, and will make it that much harder for them to meaningfully comply with FDA regulations.

(iii) Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g, reporting, recordkeeping, or labeling requirements?

The Final Rule in its present form, and specifically in relation to cigar products, is unnecessary. When Congress passed the Tobacco Control Act, and mandated the regulation of only cigarettes, smokeless tobacco and roll-your-own tobacco products, it did so against a backdrop of a history of product manipulation by the cigarette companies.[94] No claims of product manipulation have been made regarding cigars. Therefore, the need for product testing, ingredient

[92] Recently filed litigation details the inadequacy of the guidance provided to currently regulated products, as well as the overreaching and indefensible manner in which FDA has implemented premarket review to date, with absurd results. *See U.S. Smokeless Tobacco Company LLC v. United States Food and Drug Administration, et al.*, United States District Court for the District of Columbia, Docket No. 18-cv-251.

[93] FDA Actions Regarding Tobacco Manufacturers / Importers Affected by Recent Natural Disasters, available at https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm (last visited November 16, 2017).

[94] 123 Stat. 1777, 1781 sec. 1 (49).

reporting and premarket review at the level currently being required by the Final Rule is not warranted.

Further, the vast majority of cigars have carried health warnings for the past seventeen years. It is unnecessary to require companies that are signatories of the FTC Consent Decree to go through the cost and expense to change the warnings they have been providing to consumers for the past seventeen years. Instead, FDA could require all cigar products to carry the FTC Consent Decree warnings to provide a consistent warning system, but not impose such an extreme cost on the complying entities.

FDA is also requiring redundant submissions under the Final Rule. Every manufacturer of a cigars must submit ingredient reports, and if introduced after 2007, a premarket application for each product. As noted above, however, as FDA has stated that companies that "repackage and relabel" tobacco products are to be considered "tobacco product manufacturers" and are creating "new products" this has made hundreds of retail entities tobacco product manufacturers, because they take finished cigars and either combine them to make a "sampler pack" or take a box of 20 and break it into 4 "5 packs." These retailers now have to i) register as a manufacturer with FDA and list all of these products; ii) provide ingredient reports for products that the actual manufacturers of the product have already provided to FDA; and iii) apply for premarket approval for any of these products created after 2007. This is entirely redundant. The actual manufacturer of the cigars in question will have filed ingredient reports for the product and will have filed any necessary premarket approval.

(iv) Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

FDA could modify the Final Rule and still achieve the goals of the regulation, but in a much less costly manner, in two specific areas. First, FDA could adopt the FTC Consent Decree warning rotation system for cigars, and second FDA could address the premarket review process. Additionally, as FDA will be considering as part of the announced Advance Notice of Proposed Rulemaking, FDA could exempt premium cigars or regulate them differently.

First, as noted above, the vast majority of the cigar industry has been putting health warnings on cigar packages and advertisements since 2001. FDA could have adopted the FTC Consent Decree warnings and applied them to the entire cigar industry so that there would not be any products sold without the warnings. The FTC Consent Decree warnings followed the FTC Guidelines that all disclosures must be "clear and conspicuous," and the warnings that are currently on cigar products meet this standard.[95] The FTC warnings are only on one principal display panel of the package and come in six sizes based on the size of the package. The FDA warnings must be on two principal display panels and cover approximately 400% more surface area than the FTC warnings. FDA has no basis, and could not articulate a benefit, in requiring larger health warnings

[95] AUSA PCD comment at 35.

than those required by the FTC. Instead, FDA stated " [r]eliable evidence on the impacts of warning labels on users of cigars...does not, to our knowledge, exist."[96]

Second, FDA could address the premarket review process in two different ways. FDA has stated that it will continue to use the February 15, 2007 predicate date for all newly deemed products, even though doing so will end up regulating the newly deemed products much more harshly than cigarettes. If FDA chose April 25, 2014, as the predicate date for newly deemed products, cigars would be on an equal footing with cigarettes – the products Congress initially sought to regulate. CAA made this argument to FDA in its comments to the Proposed Deeming Rule, but instead FDA choose to adopt the harshest and most onerous regulatory option it could.[97]

Section 2 above, describes the different ways in which the Tobacco Control Act both requires FDA, and vests authority in FDA, to regulate different tobacco products according to the needs of those products. FDA has already acknowledged this by proposing a product standard for smokeless tobacco, and announced its intention to issue a product standard applicable only to cigarettes. FDA also requires different HPHC testing for cigarettes, smokeless tobacco and roll-your-own tobacco. The Tobacco Control Act itself only banned characterizing flavors (other than menthol) in cigarettes. Premarket review should be no different. Each category of products should have requirements that are unique and "appropriate" to it. Current FDA Guidance in SE Reports makes no distinction amongst products. However, in order to reduce the costs of regulation and use "appropriate regulatory controls" FDA should outline the substantial equivalence requirements for each individual tobacco product.[98]

FDA could also provide meaningful guidance as to both what the content of a SE Report should be for cigars, and what FDA will need to find two cigars substantially equivalent to one another. As of now, FDA has shown every indication of requiring the exact same information for cigars in SE Reports as it does for cigarettes. However, FDA cannot justify doing this for products where there have not been claims of product manipulation. Instead, FDA should adopt a system for cigar SE Reports that actually looks at the basic characteristics of the two cigar products. In making a substantial equivalence determination FDA should look at: (1) cigar composition; (2) cigar size; and (3) whether the cigar has additives. The composition of the cigar could include three parts: (1) the type of tobacco (e.g., dark, air cured); (2) the type of filler (e.g. long filler); and (3) the type of wrapper (e.g. whole leaf). The cigar size could include length and ring gauge of an

[96] FRIA at 62.

[97] *See* CAA comment at 8. FDA determined that "it lacks the authority to change the grandfather date, which is set by statute," 81 Fed. Reg. at 28,993. However, FDA has taken a contrary position on other things. The Tobacco Control Act states that all product labels must contain "an accurate statement of the percentage of the tobacco used in the product that is domestically grown and the percentage that is foreign grown tobacco." 21 U.S.C. §387c (a)(2)(c). However, FDA has decided to use its enforcement discretion to not require companies to comply with this statutory requirement stating "FDA does not intend to enforce the Section 903(a)(2)(c) of the FD&C Act for those products that are made or derived from tobacco." Draft Guidance for Industry: Interpretation of and Compliance Policy for certain label requirements; Applicability of certain Federal Food, Drug and Cosmetic Act Requirements to vape shops. At 5. (January 2017). It is clear that FDA can use enforcement discretion when it chooses to do so.

[98] *See* 123 Stat. 1777, 1782, sec 3 (8).

individual cigar. If the FDA were only to look at these characteristics between predicate and new cigars then perhaps the FDA's estimate of $22,000 per report could be achieved.[99]

Finally, as already being contemplated by FDA, FDA could exempt premium cigars from regulation, or regulate them differently from other tobacco products. Premium cigars represent only a small fraction of the total cigar market, yet a large quantity of the skus in the cigar market. Premium cigar smokers are an older population who use premium cigars infrequently. As a recent publication by FDA researchers noted, "those smoking premium cigars tended to differ from those smoking non-premium cigars, cigarillos, and FCs including having users with higher socio-economic status, lower smoking frequency, different purchasing behaviors (e.g., where and for how much cigars were bought) and reasons for use."[100] FDA should exempt these products from regulation, or should create a regulatory regime for them that would exempt them from premarket review and HPHC testing requirements.

(v) What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

FDA should consider what the actual, quantifiable benefits are to public health due to requirements of the Final Rule in light of the actual, quantifiable costs to industry in complying with the regulation. When the Final Rule is examined under this rubric, it becomes immediately apparent that this rule is ripe for reform. This concept -- of quantifying benefits in relation to costs -- is not new. In fact, Executive Order 12866 requires that:

> Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.[101]

This defining principal was reaffirmed over a decade later in Executive Order 13563, which stated that "each agency...must propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to justify)."[102] CAA understands that the FDA has been given the statutory authority to regulate tobacco products, and has chosen to deem all tobacco products subject to its authority. It must do so, however, in a way that truly examines the purported benefits of the regulation and its actual costs. FDA failed on both of these accounts.

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[99] FDA should also consider whether retailer created cigar samplers and 5-packs, as well as the blending of finished pipe tobacco or breaking bulk pipe tobacco into smaller packages, requires a full SE Report, or whether these products could be exempt from the SE process or could file an abbreviated application.

[100] Corey CG et al. U.S. adult cigar smoking purchasing behaviors, and reasons for use according to cigar type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014. Nicotine Tob. Res. 2017 Sept. 15 epub ahead of print.

[101] Exec. Order No. 12,866, 58 Fed. Reg. 735 (Oct. 4, 1993).

[102] Exec. Order No. 13,563, 76 Fed. Reg. 3821. (Jan. 18, 2011).

In the required Final Regulatory Impact Analysis FDA repeatedly states that it cannot "quantify the benefits of the final rule."[103] Further, FDA states that "[r]eliable evidence on the impacts of warning labels, premarket review, and marketing restrictions on users of cigars...does not, to our knowledge exist."[104] FDA has admitted that it has no knowledge of the impacts of these regulatory efforts and it cannot quantify the benefits of the Final Rule.

FDA severely underestimated the volume of entities that would be regulated under the Final Rule as well as the volume of products that would be regulated. In discussing this potential underestimate for cigars FDA stated:

> Given the difficulties with reliably estimating the magnitude of possible understatement from using the counts from the large internet retailers, we opt to use the estimate of 7,500 products, acknowledging its potential for undercount but expecting that it provides a good representation of the parts of the market for cigar products likely to be grandfathered or submitted for premarket review.[105]

Therefore, rather than work to "reliably" estimate the actual number of products in the market, FDA just said this provides a "good representation." This cannot be appropriate from a regulatory agency that is going to cost many people their jobs and cause many businesses to close their doors.

FDA acknowledged they made inadequate estimates regarding the number of cigars in the market, yet they made the following statements about market exit:

> Some manufacturers and importers may cease to sell products in the U.S. rather than bear the cost of complying with this final rule. In particular some low-volume cigar...manufacturers may cease to offer their products in the U.S.[106]
>
> "...products with low sales volume, products with small-batch production runs, and low-volume products sold only in specialty retail outlets and other channels. We expect such product will exit the market as a result of this rule."[107]

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[103] *See* FRIA at 67.

[104] *Id.*

[105] *Id.* at 75.

[106] *Id.* at 70 (emphasis added).

[107] *Id.* at 75 (emphasis added).

> It may not be profitable for firms to bear the per-product costs of this final rule for all products currently marketed....Our analysis reflects a significant degree of product exit and consolidation.[108]

Executive Orders 12866 and 13563 make clear that an agency is to undertake a meaningful cost benefit analysis when rulemaking. FDA may have written a 156 page Regulatory Impact Statement, but based on the above statements it did not undertake a meaningful cost benefit analysis. A rule where there are no "quantifiable benefits" but discusses "significant degree of product exit" and manufacturers "ceasing" to offer products does not transparently attempt to make sure that regulation is no more costly than necessary.

The Final Rule should be selected and prioritized as a regulation for repeal, replacement or modification because its unstated benefits cannot be justified by the crushing costs on industry.

5. FDA and the Administration Have Already Modified the Final Rule and Other Similarly Situated Rules When Additional Work Was Necessary

FDA itself has already acknowledged that the Final Rule as originally written is in need of modification. FDA, on its own initiative, extended both the Domestic Manufacturer Registration and Product Listing Deadline and the Ingredient Reporting deadlines by six and twelve months respectively. These deadlines were originally December 31, 2016 and February 8, 2017 respectively and FDA moved them to June 30, 2017 and August 8, 2017 respectively. FDA then moved all compliance deadlines for an additional three months. FDA then moved the ingredient reporting deadline an additional six months.[109] Additionally, FDA announced that it was going to use its enforcement discretion and not require any tobacco products to comply with section 903(a)(2)(C) of the Tobacco Control Act.[110]

Finally, in July 2017, Commissioner Gottlieb announced a "new plan for nicotine and tobacco regulation." In this announcement, FDA stated that it was moving the deadlines for SE Reports until 2021, and was changing its policy to allow products that have submitted SE Reports to remain on the market until FDA makes a determination on the application. Even more importantly, Commissioner Gottlieb noted that "part of CTP's task [in the new plan] is to reconsider aspects of the implementation of the final deeming rule."[111]

As noted above, FDA also announced two Advance Notices of Proposed Rulemaking that may have dramatic impact on cigars and pipe tobacco. First, FDA is considering whether to exempt premium cigars from regulation, or to regulate them differently. It is this effort that lead a federal court judge hearing a cigar industry challenge to the Final Rule to declare that FDA "doesn't have

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[108] *Id.* at 78, 80 (emphasis added).

[109] *See supra* notes 65 and 66.

[110] Guidance for Vape Shops, *supra* note 85. Once again demonstrating that there are certain provisions of the Tobacco Control Act that FDA has determined it can use "enforcement discretion" to change. It has just not opted to use this "enforcement discretion" in relation to change the predicate date or changing the user fee structure.

[111] Protecting American Families: Comprehensive Approach to Nicotine and Tobacco. Remarks of Scott Gottlieb, M.D., July 28, 2017. Available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last visited November 16, 2017).

its ducks in a row." Second, the agency is considering how and whether to regulate flavors, the action of which could dramatically impact the cigar industry.

The cigar industry is not the only one that has asked for delays and modifications of rules to try to make the costs appropriate to the regulation. In October 2017, FDA announced that it was extending the compliance dates for the Food Labeling regulations by two years.[112] FDA stated it was taking this action because "after careful consideration, we have tentatively determined that additional time would help ensure that all manufacturers covered by the rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules."[113] Further FDA noted it took this action "as a means to balance the importance of ensuring that industry has sufficient time to comply with complex new requirements, and the importance of decreasing costs, against the importance of minimizing the transition period."[114] Here, FDA recognized a crushing and new burden to industry and sought a compromise position to help "decrease costs" and allow industry time to comply. The same logic should be applied to modify the Final Rule to allow the cigar industry both time to comply and an ability to minimize costs.

6. Conclusion

For the reasons and ways set forth above, CAA requests that FDA repeal, replace or modify the Final Rule in accordance with Executive Orders 13771 and 13777.

Respectfully submitted,

Craig P. Williamson

Craig Williamson
President
Cigar Association of America, Inc.

[112] Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Service Sizes of Foods That Can be Reasonably Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates. 82 Fed. Reg. 47,753.

[113] *Id.*

[114] *Id.* at 45,754.

Exhibit A

Evaluation of the Burden Reduction Opportunities In the Food and Drug Administration's Final Rule: Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act

Prepared on Behalf of the
Cigar Association of America

Submitted by:

January 2018

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Evaluation of the Burden Reduction Opportunities In the Food and Drug Administration's Final Deeming Rule

1. EXECUTIVE SUMMARY

Policy Navigation Group (PNG) prepared this review of the final Regulatory Impact Analysis (RIA) for U.S. Food and Drug Administration (FDA) rule entitled *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act*.[1] We evaluate the RIA to evaluate the impact on the cigar industry and to identify available opportunities to reduce the burden of the rulemaking.

Since FDA promulgated the rule, the Administration has issued two Executive orders that have launched new regulatory review processes under Executive Orders (E.O.) 13771 and 13777.[2,3] Through E.O. 13771, the Administration established a regulatory budget and required that regulatory agencies submit a proposed regulatory budget for along with its fiscal budget proposals to the Office of Management and Budget (OMB). For Fiscal Year 2017, E.O. 13771 established a regulatory budget of zero, meaning that the regulatory burden caused by new final rules had to be offset by changes that at least offset this new regulatory cost.

To implement E.O. 13771, Executive Order 13777 charges FDA with identifying existing regulations that:

(i) Eliminate jobs, or inhibit job creation;
(ii) Are outdated, unnecessary or ineffective;
(iii) Impose costs that exceed benefits;
(iv) Create serious inconsistencies or otherwise interfere with regulatory reform initiatives and policies;
(v) Rely in whole or in part on data, information or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or,
(vi) Derive from or implement Executive Orders of other Presidential directives that have been subsequently rescinded or substantially modified.

The rules FDA identifies using these criteria under E.O. 13777 are required to be considered for repeal or modification under the agency's regulatory budget (allocation) under E.O. 13771. FDA has

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[1] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

[2] 82 FR 9339

[3] 82 FR 12285

issued a notice requesting ideas from the public for candidate regulations and guidance documents for regulatory revaluation and burden reduction.

In addition, in December 2017, OMB released each agency's regulatory allocation for Fiscal Year 2018. The Department of Human Health Services (HHS) is required to reduce annualized net burden by $28.7 million by September 30th, leading to a present value reduction in regulatory compliance costs of $410 million. To meet its allocation, HHS, and its component agencies like FDA, must identify opportunities for regulatory burden reduction over this year.

To determine whether the Deeming Rule offers such opportunities, we examine FDA's RIA and to evaluate whether it meets the E.O. 13777 criteria. We limit our review to the provisions of the rule that have not yet gone into force and therefore present opportunities for avoid pending regulatory burden. First, we find that the RIA substantially underestimated the likely regulatory burden on the cigar industry and on consumers. Second, the RIA has deficiencies that preclude accounting for the full regulatory burden. The principal deficiencies include the following:

- FDA's description of the future market structure and future products is based largely on assumptions. Inconsistent with HHS and OMB guidance, the RIA fails to consider important consumer costs from likely post-regulation market adjustments.[4]
- The substantial cost on certain segments of the cigar market is likely to lead to substantial reduction in the variety of products on the market. FDA underestimated the consumers' loss from the reduction in variety.
- Although the rule prompts a mandatory duty to report harmful and potentially harmful constituents, the RIA excludes the cost of composition testing. FDA's refusal to estimate costs when promulgating a standard - even when the final form of the requirement is uncertain - is inconsistent with federal economic analysis requirements and the practice of other agencies.[5]
- In assuming all new products will automatically qualify for Substantial Equivalence Demonstration, FDA likely underestimates the cigar industry's compliance cost by not providing adequate justification or breakdown for its burden estimates.

The RIA provided by FDA quantifies only cigar producers' compliance costs, omitting the additional social costs affecting consumers as well as small businesses via market adjustments.

This report discusses the major issues with the RIA in more detail, proposes some alternative approaches for the rule's social costs, and recommends approaches to more accurately characterize the regulatory burden. A partial re-estimate of the regulatory burden is presented in Table ES-1.

[4]See White House, Office of Management and Budget, "Circular A-4: Regulatory Analysis"; Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, "Guidelines for Regulatory Impact Analyses."

[5] White House, Office of Management and Budget, "Circular A-4: Regulatory Analysis"; U.S. Environmental Protection Agency, "Guidelines for Preparing Economic Analyses."

The regulatory compliance costs for the non-premium market is about $50-$100 million for this initial compliance period. This value underestimates the full costs for this market since the ongoing costs are omitted as well as the loss of consumer surplus.

The regulatory costs for the premium market depend on the market choices of firms and of consumers. If firms reduce product offerings from 6,000 to 1,000, the combined consumer surplus loss is between $3.5 million (see Table 16) and 2,300 million per year (see Table 1). The initial compliance costs are $25 million (See Table 15).

Table 1: Summary of the Rule's Initial Compliance Costs and Consumer Surplus Loss

Cigar Category	Initial Regulatory Compliance Costs (million)	Consumer Surplus Loss
Non-Premium	$50-$100	Not estimated
Premium	$150-$300	$3.5 to $2,300 million per year[6]

With well over $100 million in likely costs on the premium cigar industry and its consumers alone the rulemaking imposes an economically significant burden. The rulemaking has a significant effect many businesses, likely lead to substantial employment impacts. It also has a significant effect on a substantial number of small businesses. Since the rulemaking's effect meet some of the E.O. 13777's criteria, the rulemaking provides a substantial opportunity for FDA to reduce regulatory burden.

[6] Assuming a reduction of 5,000 SKUs

2. INTRODUCTION

Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the Food and Drug Administration (FDA) is granted authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.[7] The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, allows FDA to "deem" other tobacco products subject to the FD&C Act. Consequentially, the final rule, promulgated on May 10, 2016, deems cigars as meeting the statutory definition of "tobacco product" and now subject to the FD&C Act and its implementing regulations.

Requirements that now apply to the cigar industry include establishment registration and product listing, ingredient listing, labeling requirements, prohibition of free samples, product testing and warning statements for packages and advertisements.[8] FDA quantifies the total costs over 20 years for all new deemed products at approximately $988 million at a three percent discount rate and $817 million at a seven percent discount rate. However, FDA admits to excluding unquantified costs attributable to the final rule, including the following: consumer costs due to loss of product variety or potentially higher prices; costs for testing for harmful and potentially harmful constituents; costs for clinical testing to support substantial equivalence reports; market adjustment and exit; and more.[9]

The following table summarizes FDA's estimated costs for cigars for the major provisions:

[7] Food and Drug Administration, "21 CFR Parts 1100, 1140, and 1143 Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule."

[8] Food and Drug Administration, "Certain Tobacco Product Compliance; Deadlines Related to the Final Deeming Rule; Guidance for Industry."

[9] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

Table 2: Present Value of Quantified (Private Sector and Government) Costs

Provision	Upper Bound (3%) 2016 $	Average Costs per Cigar SKU 2016 $
New Product Submission Requirements	$93,100,000	$12,000
Label Changes	$176,400,000	$22,000
Subtotal	$269,500,000	$34,000
Other Costs	$30,200,000	$4,000
Total Costs	$299,700,000	$37,000

For each item in Table 2, we then divide the cost by the 8,000 cigar SKUs that are estimated to have been on the market in a typical pre-regulatory year.[10] Table 3 shows FDA's estimated compliance costs for cigars by the major provisions during the initial compliance period and, thereafter, annually:

- Premarket requirements reflect the cost of obtaining marketing authorizations based on FDA's count of 2,625 newly deemed cigar products applying for marketing authorization (of the 7,500 cigar products at baseline, 60 percent are expected to be grandfathered) and a weighted average cost per product of $6,560 for cigars.[11]
- Annual registration and product listing includes the estimated costs - first for years one through two, then for years three through twenty - incurred by owners and operators of establishments to register their establishments and submit product listings.
- Ingredient listing reflects the cost for tobacco product manufacturers and importers required to submit listings of all product ingredients by brand and by quantity for each brand and sub-brand.
- Labeling presents the estimated cost of changing cigar labels to six versions of every new label are required and warning statement provisions: the first year includes major labeling changes such as printing plates and prepress activities for adding or enlarging warning statements; after the first year, continued operation of equal random point-of-display will result in incremental ongoing yearly administrative and recordkeeping costs.

[10] Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911." The CAA estimate was made in 2014, however, in 2016, after the Final Rule was enacted a large number of SKUs entered the market, which increased the total cumulative number of SKUs well above 8,000. In 2016, prior to the regulation, companies placed an additional number of SKUs on to the marketplace. This marketing positioning increased the total cumulative number of SKUs well above FDA's estimate of 8,000.

[11] In 2016, in FDA's RIA, the baseline number of cigar products (SKUs) was estimated in 7,500.

Table 3: Total Initial Compliance Costs by Provision for Cigars Market Segment

Provision	Total Cost during Initial Compliance Period	Annual Cost After Initial Compliance cost
Premarket Requirements	$17,220,000	$4,420,000 - $5,907,000
Annual Registration and Product Listing	$22,000 - $65,000	$4,000 - $13,000
Ingredient Listing	$1,139,000	$47,000- $94,000
Labeling	$30,202,000- $101,400,000[12]	$520,000 - $3,600,000[13]

Values may not sum due to rounding

Project Scope

This report systematically reviews FDA's final Regulatory Impact Analysis (RIA) and documents the principal ways in which the analysis falls short of White House's Office of Management and Budget (OMB), U.S. Department of Health and Human Services (HHS), and other regulatory analysis guidance. As part of this process, each flaw is reviewed and compared with the best practice recommended by these authoritative guidance documents.

In addition to identifying the flaws, two quantitative analyses are conducted. First, for some of the major methodological flaws or omissions, we develop more accurate values to estimate the regulatory costs for the cigar industry. We identify the key issues that can be revised quantitatively and develop partial re-estimates for them. The partial re-estimate demonstrates that the final RIA substantially underestimates the rulemaking's cost for the cigar industry and for consumers.

Second, we gather publicly-available revenue data for small business in the cigar manufacturing and distribution system. We use both the FDA compliance cost estimate and PNG's partial re-estimate to calculate the economic impact using the metrics in HHS's guidance and metrics commonly used by other federal agencies. Presenting the economic impact of the rule in comparable terms will more clearly demonstrate the rule's substantial impact on small businesses.

Structure of This Analysis

The data, assumptions, and conclusions presented in this report are those of Policy Navigation Group and do not necessarily reflect the opinions of the Cigar Association of America (CAA). The purpose of this report is to evaluate whether FDA's economic assessment reflects the best available principles for economic analysis. Our estimates do not evaluate the social benefits of the regulation, do not offer commentary on the medical evidence concerning tobacco use, or do not comment upon potential health impacts associated with cigar smoking.

The report is structured as follows:

[12] Cost of changing cigar labels when six versions of every new label are needed.

[13] Incremental annual costs of equal random display.

1. We provide an overview of the rule's universe and the key baseline assumptions for the analysis.
2. We discuss FDA's failure to quantify how the future post-regulation market structures will be impacted by product withdrawals and likely consumer surplus loss.
3. We highlight how FDA assumes no cost imposed by the requirement of companies to conduct testing in compliance with harmful and potentially harmful constituents (HPHC) reporting.
4. We examine how FDA's cost estimates for new products to complete Substantial Equivalence (SE) Demonstration reports is based on assumptions that lack justification and clarity. Namely, we look at FDA's assumptions that most new products will qualify under SE and that companies will not have to conduct laboratory testing to fulfill SE demonstration requirements.
5. We offer an analysis of the market adjustment, the lost consumer surplus, and the economic impact resulting from the regulation.

3. THE PRE-REGULATION CIGAR MARKET AND GENERAL BASELINE ASSUMPTIONS

We rely on the estimates provided by the FDA in its RIA for the following data and assumptions about the pre-regulation cigar market:[14]

- Number of cigar brands;
- Number of cigar manufacturers;
- Number of cigar importers;
- Typical number of products per brand; and,
- Typical number of packaging variations by brand.

To estimate the size of the cigar industry in terms of revenue and how revenue is subdivided into premium and non-premium products, we use Cigar Association of America (CAA) and MarketLine data and model different scenarios.[15] For the number of cigar products (Stock Keeping Units, or, SKUs), including how they are broken down into premium and non-premium cigars, we use publicly available estimates provided by the CAA.

New SKUs are regularly created by cigar brands to be used in future products. It is customary in the cigar industry to have multiple product presentations and formulations for one single brand. The number of this type of SKUs can exceed over 1,000 units (SKUs) per brand.[16] In addition, there are dormant SKUs, such as those related to limited editions of cigars that are no longer being produced, that are still in the market. In response to this rulemaking, cigar producers introduced a significant number of SKUs in 2016. As a result, there is substantial uncertainty as to the number of SKUs that companies will bring to compliance with the regulation. For this analysis, we will assume a range of 8,000 to 16,000 SKUs in the cigar marketplace.

To calculate the number of product combinations per brand, we use FDA's estimate that each brand has 4.4 products and each product has 1.5 packaging variations.[17] Thus, on the assumption that there are 8,000 -16,000 cigar SKUs in the market and 1,100 brands, each brand will have on average 7.3-14.6 product combinations (e.g., 8,000/1,100).

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[14] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

[15] MarketLine, "Tobacco in the United States"; Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

[16] Minato, "Six Things: What FDA's 2021 Delay Means for Cigars."

[17] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

The cigar market is segmented, broadly speaking, into premium and non-premium segments. In terms of products, we assume that there are 8,000 -16,000 SKUs in the market prior to regulation.[18] As discussed in Section 8, to obtain a better estimate of the regulatory cost by including the consumers' lost benefits, we examine in more detail the premium cigar market. We therefore require an estimate of the number of premium cigars sold and the number of premium cigar SKUs.

From a revenue perspective, the total size of the cigar industry in the United States represents approximately $7 billion in 2016.[19] From this total, approximately 2.5 percent of the market is premium ($175 million) and the remainder 97.5 percent is non-premium ($6.8 billion).[20]

Since cigars have different price points, we divide cigars sold into four price categories: $2-$4, $4-$6, $6-$10, over $10. These price categories are based on data from the International Premium Cigar and Pipe Retailers Association (IPCPR).[21] For each of these categories, IPCPR provides percentages of the best-selling range (i.e. $2-$4=5 percent, $4-$6=78 percent, $6-$10=15 percent, over $10=2 percent), based on information reported by its members.

The next step is to estimate the number of cigars sold in each price category. The U.S. Treasury collects data on cigar domestic and production and imports. Cigar imports are further subdivided into categories based on their declared value. Specifically, there are five trade codes for large cigars (USTSA2402.10.3030 to USTSA 2402.10.8080). The U.S. Treasury groups these five categories of large cigars into two values reported each month. One category is almost 15-20 times larger than the other category. We assume that the smaller category contains the premium cigar imports.

The smaller Treasury category constitutes imports of large cigars in trade categories USTSA 2402.10.8050 and USTSA 2402.10.8080. Trade category USTSA 2402.10.8050 is defined as large cigars with an import price of between $0.23 and $0.76; category USTSA 2402.10.8080 are cigars with imported value greater than $0.76. We obtained monthly declared imported value in each trade category for December 2016-December 2017.

We assume that all cigars in these trade codes have a more expensive retail price. We then can estimate the retail price of premium cigars imported that have a value greater than $0.76. We first subtract the number of estimated for the $6-$10 category from the total imports in the Treasury category. Using the two price ranges, to bring the annual total to $175 million, the mean retail prices for these two categories is assumed to be $6 and $10.

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[18] Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

[19] MarketLine, "Tobacco in the United States."

[20] Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

[21] International Premium Cigar & Pipe Retailers Association, "Premium Tobacconist Member Profile."

Table 3 provides an overview of the main pre-regulation values we use in this analysis:

Table 4: Major Pre-Regulation Market Values

Pre-Regulation Market Description	Estimate
Number of Cigar Brands	1,100
Number of Cigar Manufacturers	113
Number of Cigar Importers	216
Number of Cigar Products (SKUs)	8,000 - 16,000
Number of Products by Brand	4.4
Number of Product Combinations (SKUs) per Brand	7.3 - 14.6
Total Revenue of the Cigar Industry	$7 billion
New Product Rate	15%
Number of New Products by Brand	1.10

For the number of new cigar products that would have been introduced without FDA's regulation, we employ data from Rueda Media.[22] From this publicly available database we extract the total number of cigar brands that were released, planned to be released, or scheduled to be released in the market during 2016. The total number of new products was 800, which corresponds to 1,200 product variations or SKUs (800 * 1.5). The baseline new product rate is estimated to be 15 percent (1,200/8,000).

In addition, we calculate the number of new cigars by brand by multiplying the range of current SKUs (8,000 - 16,000), multiplying it by the new product rate (15 percent), and dividing the result by the current number of brands (1,100). Table 4 presents the number of new cigars by brand:

[22] Rueda Media, LLC, "2016 Cigar Release List - Halfwheel."

Table 5: Estimate of New Cigar Products

Post-Regulation Market Description	Estimate
New Product Rate	15%
Number of New Products by Brand	1.1 -2.2

4. FUTURE MARKET STRUCTURE AND PRODUCT AVAILABILITY

a. SUMMARY OF FDA APPROACH

The FDA deeming rule changes the market for cigars, causing shifts in cigar supply and demand. FDA simply posits the future market structure. FDA assumes that five percent of existing products will cease being sold eventually due to regulation. With regard to the rate of new tobacco products, In the final RIA, FDA estimated that new products seeking authorization annually will be approximately five to ten percent of the number of products estimated to remain on the market.

b. ERRORS WITH FDA APPROACH

FDA makes the flawed assumption that market exit is exogenous to the regulation's cost. In the RIA, FDA assumes that five percent of products will be withdrawn from the market. FDA should instead note a regulated market in the baseline generally meets adjusted consumer preference. The current market is not "free" due to state regulation, federal and state taxes, and other constraints on product use. However, current purchasing patterns are the most readily-available measures of consumer willingness-to-pay for cigars. The diversity of products, rates of new product introduction, and consumer experience have arisen to meet consumer demand.

FDA's regulation will raise cigar manufacturers' operating costs. In a competitive market, firms then try to raise their prices to offset some of these increased production costs. Consumers, in turn, react to the price increases and reduce their purchases of cigars according to the price elasticity of demand. Lower consumer purchases then in turn reduce producers' revenue, causing them to either stop selling money-losing products or cease operations. Once producers decide on their compliance strategy, the social costs and economic impact of the rule are known. This dynamic response to regulation predicts producer/product exit.

FDA does not consider that, as companies ultimately change their products, consumers will no longer see their preferred options, and many will likely switch. As a result, consumers overall will suffer from no longer seeing their preferred brands. Thus, product withdrawal causes consumer welfare loss. FDA should compute the cost per product or cost per company to compare it to actual companies' revenues in order to quantify the impact of company closure, brand consolidation, and product withdrawals from the market.

c. ALTERNATIVE APPROACH

We adopt dynamic modeling of consumer and producer response to regulation in this analysis. To do so, we calculate the costs of complying with each individual requirement of the rule, simulate consumer response to price increases, and the combined effect of lower demand and of higher operating costs on cigar manufacturers. See Section 8.

5. HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS

a. SUMMARY OF FDA APPROACH

Under the FD&C Act, manufacturers or importers are required to submit a listing of constituents in each tobacco product, and the smoke if possible, that are identified by the FDA as harmful or potentially harmful (HPHC) by brand and quantity. FDA intends to enforce the required HPHC testing and reporting requirements three years after the effective date of the final rule for cigars and other newly-deemed products.

FDA states that it plans to issue additional guidance on HPHC reporting, as well as a separate testing and reporting regulation, but does not provide details on how they will approach HPHC reporting.[23] The final RIA does not estimate any costs for this regulatory requirement. The effective date of compliance for this provision is November 8, 2019 or, for products entering the market after November 8, 2019, 90 days prior to marketing.[24]

b. ERRORS WITH FDA APPROACH

FDA's rule sets the requirement for companies to submit listings of HPHC imposes the costs of conducting product constituent and smoke tests. While future FDA actions will shape the magnitude and timing of these costs, social costs are triggered by the final rule.

FDA's approach of ignoring these costs is inconsistent with other agencies. For example, the U.S. Environmental Protection Agency (EPA) under the Clean Air Act sets National Ambient Air Quality Standards (NAAQS). These NAAQS air quality concentrations are not direct regulatory standards; states develop state implemental plans that contain the state's strategy of emission limits on specific industries, transportation projects, and other programs to meet the NAAQS in their area. EPA estimates the potential social costs when it sets NAAQS standards, even though the specific requirements are set later by states.[25] EPA does so because the NAAQS establishes a regulatory obligation; it is inconsistent with OMB guidance and other agency practice for FDA to ignore the regulatory costs simply because they are uncertain.

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[23] Food and Drug Administration, "21 CFR Parts 1100, 1140, and 1143 Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule."

[24] Food and Drug Administration, "Certain Tobacco Product Compliance; Deadlines Related to the Final Deeming Rule; Guidance for Industry."

[25] U.S Environmental Protection Agency, Office of Air and Radiation, "The Benefits and Costs of the Clean Air Act from 1990 to 2020."

In addition, the rule does not include organization costs to respond to FDA inquiries about the HPHC submission. FDA does not present any evidence that this extreme assumption is the most likely outcome. Given that an international standard and testing protocol for large cigar testing has not been developed, development of data may need to wait until this protocol is approved. Since the method will be very new, it is likely that problems could arise. There may be limited number of laboratories ready to conduct the test. Laboratory personnel may need training, leading to greater risk of error. Reproducibility concerns may arise as different laboratories conduct the tests. Finally, FDA staff must evaluate and understand the new testing protocol, the minimal quality standards, the limits of detection, and other testing parameters.

All of these factors increase the probability that FDA may at least initially require multiple resubmissions and testing to fulfill this requirement. A more reasonable assumption is that FDA requires more information on a certain percentage of submissions. The RIA should have included these costs.

c. ALTERNATIVE APPROACH

It is difficult to adequately quantify the costs to industry of cigar testing. This is for two specific reasons. First, there are not established International Organization for Standardization (ISO) methods for cigar smoke testing, nor are there established third party methods for cigar smoke testing for all cigar products. Second, FDA has yet to identify what HPHCs will be required for cigar testing.

While there are established methods and ISO standards for testing cigarette smoke, no such methods or standards exist for cigar smoke. The two products are very different both in composition, shape and size and use, and therefore any methodologies or standards available for cigarette smoke testing cannot be used for cigar smoke testing. CORESTA (Cooperation Center for Scientific Research Relative to Tobacco) is the leading scientific body relating to tobacco science issues. CORESTA has various working groups that work on establishing testing protocols for tobacco products. While there are CORESTA methodologies relating to some cigar products, even these are currently undergoing review and update by CORESTA working groups.[26] Further, CORESTA has three other ongoing projects, in addition to this review and update, to try to establish protocols and testing methodologies for larger, and especially premium cigar, products.[27] None of these methodologies has been completed, none have received ISO certification, and none have been accepted by FDA.

FDA originally published a list of 93 HPHCs.[28] It then published a Guidance document which outlined the required HPHC testing for cigarettes, smokeless tobacco, and roll-your-own tobacco. Table 5 below lists the different HPHC testing required for the three different products.

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[26] Cooperation Centre for Scientific Research Relative to Tobacco, "Active Projects | CORESTA."

[27] Ibid .

[28] U.S. Food and Drug Administration, "Compliance, Enforcement & Training > Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List."

Table 6: Potentially Required Tests Under the Rule's HPHC Provision[29]

Cigarette Smoke	Smokeless Tobacco	Roll-your-own Tobacco and Cigarette Filler
Acetaldehyde	Acetaldehyde	Ammonia
Acrolein	Arsenic	Arsenic
Acrylonitrile	Benzo[a]pyrene	Cadmium
4-Aminobiphenyl	Cadmium	Nicotine (total)
1-Aminonapthalene	Crotonaldehyde	NNK
2-Aminonapthalene	Formaldehyde	NNN
Ammonia	Nicotine (total and free)	
Benzene	NNK	
Benzo[a]pyrene	NNN	
1,3 Butadiene		
Carbon Monoxide		
Crotonaldehyde		
Formaldehyde		
Isoprene		
Nicotine (total)		
NNK		

[29] U.S. Food and Drug Administration, "Compliance, Enforcement & Training > Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List."

NNN		
Toluene		

FDA creates product specific lists for HPHC testing. To date, no list has been provided for cigars, so it is impossible to determine which HPHCs will be required to be tested in cigars. Companies have received costs estimates from independent testing laboratories of $5,000- $20,000 per product for HPHC testing, depending on the protocols required and the number of HPHCs to be tested.

With regard to HPHC testing costs, given the uncertainty in the potential requirements, it is only possible to use a hypothetical value to assess the potential costs of this provision. For this analysis, we hypothetically assume that HPHC testing costs will be $9,700. However, actual testing costs are likely to be significantly higher.

To estimate the other potential costs of HPHC, one can calculate the technical, management and clerical staff time to prepare, review and submit HPHC reports. For the purposes of this analysis, we assume that HPHC reports will require 50 percent less time than the modified costs for a substantial equivalence (SE). FDA assumed 220 hours for the SE application.

For the preparation and review of the submission, FDA's analysis fails to consider that multiple company staff will be involved in the application process, not only to prepare the submission, but also to review and record the submission. For our alternative analysis, we assume that three different labor categories are needed, one technical, one managerial, and one administrative/legal assistant. The unloaded rates we use are based on data from the Bureau of Labor Statistics for tobacco manufacturing.[30] To account for overhead, general and administrative costs, we multiply each unloaded rate by two, the same approach FDA uses.

For the HPHC report, we allocate our estimate of 110 hours between two staff members (55 hours each). Companies must contract for laboratory services, verify laboratory performance, review the results, and assemble the report. We assume that other members of the company require an additional 20 percent of the 110 hours to prepare the draft submission. Also, we assume that an administrative/legal assistant will be needed to assist in the preparation, review and recordkeeping of the submission (10 percent of the time spent by the technical staff).

The following table (Table 6) presents the rates and categories we use to estimate the labor costs of the HPHC provision:

[30] U.S. Department of Labor, Bureau of Labor Statistics, "Tobacco Manufacturing - National Industry-Specific Occupational Employment and Wage Estimates; NAICS 312200 - Tobacco Manufacturing."

Table 7: HPHC Labor Costs

Labor Category	Unloaded Hourly Rate	Fully Loaded Rate	Number of Hours
Industrial Production Manager	$53.26	$106.52	55
Chemists and Materials Manager	$30.21	$60.42	55
Administrative/Legal Assistant	$19.92	$39.84	11

To estimate the costs of this provision, we multiply the number of tests required by its unit cost. Then, we sum the corresponding labor costs by multiplying the number of hours in each category by the fully loaded rates.

Furthermore, our estimate assumes that 10 percent of applications submitted to FDA will need to be resubmitted due to rejection. Firms have a strong financial incentive to submit complete applications to sell their products. Application reconsideration would require 10 percent of the initial application labor and testing costs in case the initial application is rejected by the FDA. These assumptions may understate or overstate the actual costs. This estimate assumes that tests and harmful and potentially harmful constituents substance reports are conducted by brand and that multiple packaging combinations with the same product composition are covered in the same report.

6. PREMARKET AUTHORIZATION

a. SUMMARY OF FDA APPROACH

Deemed products must provide justification to remain on the market after the FD&C and the deeming regulation occurred. Companies may only sell grandfathered products or products that have FDA premarket authorization. To obtain premarket authorization, firms may demonstrate that their new or existing, non-grandfathered product is substantially equivalent (SE) to an authorized product. If there is not an equivalent product, companies must submit premarket authorization (PMA) application.[31]

In the RIA, FDA asserts that 60 percent of cigar products will be grandfathered and thus will not require market authorization. FDA also states that all other existing cigar products are eligible to make a SE demonstration. Manufacturers must provide information that allows FDA to determine whether a new tobacco product is substantially equivalent to that of a predicate product or an existing product on which to base comparisons. There must be a comparison of all ingredients, materials, heating sources, design feature compositions, constituents, and other features that are identified with the predicate product. Changing the number of cigars sold in a package or changing an ingredient requires to SE demonstration.[32]

FDA estimates that, on average, it will take 220 hours to complete the task of preparing and submitting a complete substantial equivalence report. The time estimated to complete the Initial Quantity Change SE Report is 185 hours and the Bundled Quantity Change SE Report is 210 hours.

b. ERRORS WITH FDA APPROACH

The RIA contains assumptions with little verifiable justification. FDA does not provide any justification that 60 percent of products qualify as grandfathered and thus do not require premarket authorization. FDA's burden estimate for an SE application does not include a breakdown of the component cost or does not have citations for its SE cost estimates.

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[31] Food and Drug Administration, "21 CFR Parts 1100, 1140, and 1143 Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule."

[32] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

It also appears FDA assumes no costs for physical testing and laboratory analyses, which it appears companies are likely to be required to conduct to demonstrate a candidate product has the characteristics of predicate products. Many situations could lead to physical testing, but do not need to. For example, FDA may reasonably inquire as to whether different ingredients contain, or form when combusted, potentially hazardous constituents.

FDA's assumption is that no new cigar products will require premarket approval and will qualify under SE. However, FDA does not provide justification for this assumption. The rise of vapor technologies and non-combustion delivery systems are examples of innovation in the broader industry. By assuming that no similar innovation will occur in cigar markets, FDA likely underestimates the cigar industry's future compliance costs.

It is also unclear whether the total hours per application incorporate the time involved in communicating back-and-forth with FDA. FDA may have questions or require additional data after a company submits an SE application. Since the requirements for an SE are not known and may change over time, some fraction of SE applications will likely require multiple submissions before receiving a final FDA decision.

As previously shown in other parts of the RIA, FDA assumes that five percent of existing products drop out of the market and do not submit an SE application. As stated earlier, we use market data to estimate this percentage in this report. FDA also repeats its assumption that only one person is required to complete a submission; FDA should assume and account for more than one person, including legal and managerial staff, to write, review, and approve each submission. Lastly, FDA does not clarify what the environmental assessment entails or on what basis it estimates that it will require 80 hours per product.

c. ALTERNATIVE APPROACH

We estimate the SE application cost by assuming it has three components per application. First, companies may conduct physical product and use testing to demonstrate that a non-grandfathered product is chemically similar to authorized products. Second, the physical data is supplemented by literature reviews and other analyses. Third, managerial and legal staff review a company's draft SE submission package prior to sending it to FDA.

As discussed in the last section, firms must test every cigar product - even grandfathered products - for HPHCs. Some of this physical testing can be used to support a SE application. Therefore, companies may try to conduct just one set of constituent characterization to satisfy both requirements. In addition, some SE applications will be required when companies change package quantity. These SE applications are not likely to change the constituent composition. For these reasons, not all SE applications will require physical testing.

On the other hand, the scope of the SE application is potentially greater than the HPHC reporting. While the HPHC reporting is based on a discrete list, FDA requires companies to demonstrate that non-grandfathered products have multiple attributes equivalent to existing product. Since FDA has not issued guidance, the number of points of comparison are unknown.

We assume that 10 percent of non-grandfathered products will require the same battery of tests required for the HPHC demonstration. Firms have a strong financial incentive to develop products for which they can develop a relatively straightforward SE demonstration. The 10 percent assumption may understate or overstate the actual costs.

For the preparation and review of the submission and for the preparation of the environmental assessment (220 hours for SE application and 80 hours for environmental assessment and), FDA's analysis fails to justify the fact that various staff members will need to be involved in the application process, not only to prepare the submission, but also for review and recordkeeping purposes.

For our alternative analysis, we assume that three different labor categories are needed, one technical, one managerial, and one administrative/legal assistant. The fully-loaded labor rates for these categories is extracted from BLS data.[33]

For the environmental assessment, FDA arbitrarily indicates that 80 hours of labor time would be required to complete that process. However, FDA's analysis does not mention how this estimate is derived and does not discuss specifics on the information that needs to be provided in the assessment. Since we cannot evaluate FDA's assumptions, we allocate the 80 hours stated by the FDA into managerial and technical staff time.

For the SE application, we allocate FDA's estimate of 220 hours between two staff members (110 hours each). In its estimate, FDA does not include any time to review the submission. We assume that other members of the company require an additional time equal to 20 percent of the 220 hours to review the submission. Also, we assume that an administrative/legal assistant will be needed to assist in the preparation, review and recordkeeping of the submission (10 percent of the time spent by the technical staff).

Table 7 presents the labor categories and rates and categories used to quantify the labor-related costs of the SE provision of the rule:

[33] U.S. Department of Labor, Bureau of Labor Statistics, "Tobacco Manufacturing - National Industry-Specific Occupational Employment and Wage Estimates; NAICS 312200 - Tobacco Manufacturing."

Table 8: Estimated Labor Costs for SE Applications

Labor Category	Unloaded Hourly Rate	Fully Loaded Rate	Total Hours Needed	Environmental Assessment	SE Application Category		
					Preparation	Review	Recordkeeping
Industrial Production Manager	$53.26	$106.52	172	40	110	22	
Chemists and Materials Manager	$30.21	$60.42	172	40	110	22	
Administrative / Legal Assistant	$19.92	$39.84	17		12	4	1

To estimate the costs of this provision, we multiply the number of tests required by its unit cost. Then, we sum the corresponding labor costs by multiplying the number of hours in each category by the fully loaded rates.

Furthermore, our estimate assumes that 10 percent of applications submitted to FDA will need to be resubmitted due to rejection. Firms have a strong financial incentive to submit complete applications to sell their products. Application reconsideration would require 10 percent of the initial application labor and testing costs in case the initial application is rejected by the FDA. These assumptions may understate or overstate the actual costs. This estimate assumes that tests and reports are conducted by brand and that multiple packaging combinations with the same product composition are covered in the same report.

7. CONSUMER SURPLUS ESTIMATE

a. WHITE PAPER METHODOLOGY

In the previous sections, we have examined the increased costs to cigar producers to comply with the regulation to stay in the market. However, the social cost of the rulemaking is not only the additional costs paid by producers, but the combination of the lost producer and lost consumer surplus when market prices rise to cover the regulatory compliance costs. This fundamental principle of economics in described in more detail in both OMB's Circular A-4 and HHS Guidance on conducting a regulatory impact analysis.[34] In particular, consumers have a surplus if their value - their willingness to pay (WTP) - is greater than the market price. When prices rise due to regulation, the new price will exceed some consumers' WTP. These consumers that are not willing to pay the higher prices and instead turn to other substitute goods that they value less. This lost consumer surplus is part of the social cost of the rulemaking.

The final RIA ignores lost consumer surplus and instead estimates the size of producer costs to comply with the regulatory requirements. While many federal economic analyses also do not estimate lost consumer surplus, lost consumer surplus is more important in this rulemaking than in others for several reasons. First, the rule restricts widely-used consumer goods that have established markets, prices, and consumer demand. Lost consumer demand is much more easily measured when regulated goods are bought and sold in transparent, relatively unrestricted markets. Second, certain parts of the cigar market are comparable to markets for luxury goods. For luxury goods, the consumer's WTP can far exceed the real resource cost to make the product.[35] Using the additional cost of real resources needed for regulatory compliance will underestimate a regulation's social costs when consumers value intangibles such as the experience, the emotion, and other, non-tangible product attributes. Third, since the regulation applies to all domestic and all imported products sold in the United States, market prices must rise. Consumers cannot easily turn to unregulated imports. When regulation raises all prices in a market, lost consumer surplus becomes more important.

By estimating only the additional cost to producers, FDA's RIA underestimates social cost. In the proposed RIA, FDA deserves credit for confronting this issue and considering lost consumer surplus.[36] FDA did not carry that analysis forward in the final RIA. In the Final RIA, FDA responded the following, with regard to estimating lost consumer surplus:

> *FDA agrees that application of the concept of lost utility is complicated for products that are addictive or habitually consumed, and accepts that the approach taken in the PRIA*

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[34] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Guidelines for Regulatory Impact Analysis" See Appendix B.

[35] Hennigs et al., "Consumer Desire for Luxury Brands."

[36] Food and Drug Administration, "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis. Docket No. FDA-2014-N-0189."

> *warrants reconsideration...FDA disagrees with the view that lost utility is not an appropriate concept for analyzing regulations addressing addictive goods. Consumer surplus is central to the welfare economics framework that FDA and numerous outside experts (including many commenters) believe serves as a useful guide to assessing efficiency of policy. The Office of Management and Budget's Circular A - 4 on regulatory impact analysis includes gains and losses in consumer surplus among the issues that agencies should evaluate when relevant...In the case of the deeming rule, lack of data on usage patterns and health risks for deemed products means the empirical approach used in the White Paper cannot be used to quantify utility offsets that may be associated with the deeming rule...*[37]

In summary, FDA's response is cursory and, even if accurate, lumps all deemed products together. FDA's arguments rest upon the assumption that rule would not have to save many quality-adjusted life-years (QALYs) to break even from a public health perspective. However, if FDA's regulation could lead to a severe contraction of the cigar market, the breakeven analysis is less favorable. More fundamentally, however, FDA's approach masks the variations in lost consumer surplus across different market segments. FDA's sweeping dismissal of utility concerns precludes the opportunity to examine if less burdensome approaches would be more cost-effective for different deemed products and product segments.

FDA has sufficient information to estimate the potential loss of consumer surplus due to the regulation of cigars. The HHS put forth a methodology in its 2015 White Paper on *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*.[38] The White Paper gives an overview of the issue and starts by affirming certain economic principles. First, not all consumers using an addictive good are irrational, in the economic sense. Some consumers are fully informed of the potential risks and addictive qualities of a good or service and decide that the benefit to them exceed the costs. Second, FDA regulations that increase production costs and restrict access to tobacco product effectively raise the price of the good to the consumer.

From these principles, the White Paper divides consumers into two categories and considers their response to a regulation that creates an effective price increase:

> Figure 1 shows a graphical version of this model that underlies the framework for valuing benefits and costs of regulations. As is the norm, we include the monetary price and health and longevity costs as costs, and the consumption benefits net of withdrawal as the value to the individual, though no practical difference in results depends on whether a health harm is termed a cost or a negative benefit. The demand curve thus reflects the first two terms on the left-hand side of equation (2), and the remaining two terms are built into the cost. Because withdrawal costs vary with past consumption, so too will the value of current

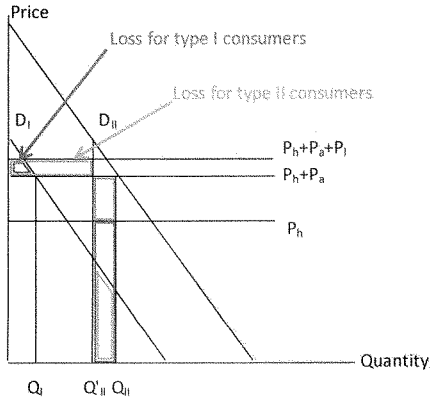
[37] U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

[38] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Policy and Evaluation, *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*, August 3, 2015.

> consumption. We start by assuming the individual has some addictive stock and draw the demand curve corresponding to that addictive stock. We return to the dynamics below.
>
> The model can be applied for both existing users of the good and for potential initiators, although the implementation differs between the two cases. Considering existing users first, we delineate two types of individuals with otherwise similar characteristics (age, gender, etc.): type I consumers who make smoking decisions in a way that is fully rational and fully informed ...; and type II consumers who have time inconsistent preferences ... or misperceive how their current actions will affect their future choices and health risks ....[39]

For non-addicted consumers who are knowledgeable of the health risks and potential consequences, HHS found that conventional economic theory applied.[40] These consumers' purchases can be assumed to be rational decisions about trade-offs. In other words, agencies can estimate the social cost of a regulation in the same manner as other goods. In Figure 1, regulation increases the direct and indirect price consumers pay, rising from P_h+P_3 to $P_h+P_3+P_t$. Type I consumers respond along demand curve D_I and reduce their consumption to below Q_I. The consumer surplus loss is shown in Figure 1.

Figure 1. Consumer Surplus Losses for Type I and Type II Consumers Due to Regulation



Source: Cutler et al[41]

[39] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Policy and Evaluation, *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*, August 3, 2015, pg. 17.

[40] Cutler, Kenkel, and Starr, "Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods."

[41] Cutler, Kenkel, and Starr.

To sort consumers into the Type I or Type II category, the White Paper applies several tests. By dividing cigarette smokers by whether they smoked within the first 30 min of being awake, HHS found that 56 percent of current smokers do not and are thus defined as Type I consumers. These Type I consumers are younger, have more educational achievement, and greater family annual income than Type II consumers.

The premium segment of the cigar market has consumers that are comparable to the Type I HHS criteria for cigarette smokers. Using the 2012 National Adult Tobacco Survey data, only 3.3 percent of premium cigar smokers smoked cigars daily; over 70 percent smoked these cigars only "rarely." More than 40 percent of regular premium cigar smokers report having never smoked cigarettes.[42][43] In terms of educational attainment, more than 50 percent of premium cigar smokers have a college degree or a higher degree. Approximately only nine percent of cigarette smokers have the same level of educational attainment. Sixty-seven percent of cigar smokers have annual family income of $50,000 per year (2012$); more than 40 percent have family income of $100,000 per year or greater.

The NATS data indicates that there is a consumer segment of the premium cigars that fits the characteristics of Type I consumers according to the HHS classification. They do not smoke cigars or tobacco products frequently enough to exhibit addictive behaviors. Their educational and income achievements suggest that they are capable of rational decisions concerning health risks and that they have sufficient disposable income to choose among available discretionary, luxury products that maximize their utility.

In this analysis, we create a quantified estimate of the lost consumer surplus for these Type I consumers -- occasional smokers who purchase premium cigars. The principle - and FDA's obligation under Circular A-4 - to estimate lost consumer surplus extends to every component of the cigar market. In fact, the HHS 2014 approach provides a clear methodology that FDA should use for all Type I and Type II cigar consumers. In this analysis, we consider the Type I consumer in the premium market to illustrate the importance of lost consumer surplus to show how much FDA underestimated the social cost of its rulemaking.

b. PREMIUM CIGAR WILLINGNESS-TO-PAY ESTIMATE

Available information about how most consumers acquire and consume premium cigars suggest that consumers' willingness-to-pay is far greater than the cigar's price. The attributes of premium cigar marketing are like other luxury goods. A multinational study of luxury good marketing and consumer preferences found consistent consumer values for luxury goods:

> *Vigneron and Johnson (2004) proposed that a consumer's decision-making process can be explained by five main factors: personal perceptions in terms of the perceived extended self,*

[42] Corey et al., "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012-2013."

[43] While no data is presented in the survey for cigarette smoking history for cigar smokers who only smoke "rarely," it is reasonable to assume that this proportion is greater than 40 percent.

perceived hedonism and nonpersonal perceptions referring to perceived conspicuousness, perceived uniqueness, and perceived quality. To acquire information regarding consumer motives and value perceptions, Wiedmann, Hennigs, and Siebels (2007) developed a four-dimensional model that explains luxury consumption through consumer perceptions of the social, individual, functional, and financial value dimensions of luxury and thus draws on and extends Bourdieu's capital theory (1986) and existing luxury research literature (Vigneron & Johnson, 2004).[44]

A consumer assesses the value of a luxury good by combining the financial, use, individual, and social value of the product and experience to the individual. The premium cigar market is structured to offer these values to consumers. Companies appeal to a consumer's financial values through price. Cigar shops, on-line resources, and public health campaigns offer functional values through information about the smoking experience and its hazards. Cigar firms, trade magazines, cigar shops and cigar bars appeal to individual values through the education process of the cigar's quality and uniqueness, via its origins and fabrication. Since premium cigars are often smoked with others, the marketing appeals to social values through opportunities to interact with others at cigar shops or cigar bars and to fulfil values of perceived conspicuousness. It is these individual and social values that are the most intangible and require the consumer to gather information about the cigar to select the one that has the best attributes for the consumer.

Consumer pay to obtain these values separately from the price of the premium cigar. To have the social experience, they pay the travel and admission costs to attend cigar events. To gain the education about the quality and unique features, they spend time and resources to be educated, whether at a cigar shop, on-line, or in discussions with others. The costs to obtain these values are part of the consumers' willingness to pay for the premium cigar luxury experience. The same behavior and WTP attributes are found for certain liquors, wines, handbags, scarves, jewelry, automobiles, and other items.[45]

Therefore, when consumers drop out of the premium cigar market due to the direct and indirect price increase due to the regulation, the consumer will shift the value of all time and resources spend on the premium cigar experience to other items or luxury goods. The lost consumer surplus likely includes the following components:

- *Value of Time to Travel to a Store.* In a small marketing survey, most infrequent consumers purchased their premium cigars at a physical location such as a tobacco store, cigar club, or other location.[46] Like other goods whose attributes are not known until they are consumed, a significant proportion of cigars are sold in traditional retail shops. As with books or wines, consumers seek out information on the different options so that they can maximize the utility of their budget. The internet has created the opportunity for consumers to gain this information and to order products with less transaction costs. However, consumers still frequent retail cigar stores to learn from other consumers and from proprietors. They spend time and funds to travel to these locations. For this estimate, we assume consumers spend ½

[44] Strehlau et al., "Consumer Value Perception of Luxury Goods."

[45] See for example, Silverstein, M.J., Fiske, N. *Luxury for the Masses*, Harvard Business Review, April 2003.

[46] Response Marketing, "Insights into Cigar Smokers and What That Means for Cigar Brand Marketers."

hour and travel a total of 15 miles per trip per cigar purchase. For the travel cost, we use the 2017 Internal Revenue Service allowable cost for business travel.[47]

- *Value of Time to Acquire Knowledge of a Preferred Cigar.* The retail and online purchasing experience is designed to give consumers knowledge of the flavor, the brand, the production history, and other elements. The analogy is to consumers' approaches to wine choices and to restaurant meal choices. Consumers will spend some time gathering information before spending that money and time. For this estimate, we assume that infrequent consumers spend one hour per purchase to gather information, to discuss options with others, and other educational activities.
- *Value of Relaxation.* From surveys, consumers smoke premium cigars alone roughly 43 percent of the time.[48] Otherwise, consumers report smoking together with friends. We assume that preparing the cigar to smoke and preparing the location at home requires ½ hour. The cigar smoking experience lasts one hour, leading to a total leisure activity of 1 ½ hours for smoking alone.
- *Value of Smoking with Others.* In the survey, respondents reported smoking with friends on golf courses, in cigar bars, at cigar shops, and in other social events. We assume that consumers must travel 15 miles to a specific event, pay an admission fee of $100, and spend on average four hours at the event. We recognize that consumers would still gain utility from these events (e.g., golf) even if they did not smoke a cigar. However, consumers have these choices today; if the quality of these activities is reduced due to the regulation, this loss of value is a cost of the rule.
- *Value of Leisure Time.* For the value of leisure time, we use the U.S. Department of Transportation (DOT)'s value for leisure time.[49] US DOT establishes a value so that it can estimate the value of transportation projects that reduce congestion and travel times. In general, for many years, DOT has found that ½ hour of a person's hourly cash wage equivalent is its best estimate for the value of leisure time. Based on a majority of occasional premium cigar consumers having household income of $50,000 per year or greater, we use a value of $25 per hour as the value of leisure time. We calculate this value as ½ of an hourly cash wage of $50 per hour, equivalent to a household income of $100,000 per year.

c. SUBSTITUTES TO CIGAR CONSUMPTION

If consumers chose not to pay the increased price for the premium cigar experience after the regulation, they will turn to substitutes. They may join whisky clubs, join fantasy sports organizations, or engage in yoga or exercise to relax at home. In particular, the regulation does not take away the consumer's time; it just shifts that time to a less-valued activity for that consumer. The loss in consumer surplus is the difference in WTP between the cigar experience and the closest substitute activity. We assume that consumers suffer a $2 loss per hour when they shift to a lower-valued activity due the regulatory-induced price increase.

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[47] Internal Revenue Service, "2017 Standard Mileage Rates for Business and Medical and Moving Announced."

[48] Response Marketing, "Insights into Cigar Smokers and What That Means for Cigar Brand Marketers."

[49] U.S. Department of Transportation, Office of the Secretary of Transportation, "2016 Value of Travel Time Guidance."

d. SUBSTITUTES IN THE CIGAR MARKET

One of FDA's arguments in the RIA is that consumers will not miss the predicted loss of current market variety due to FDA's claim that different cigar products are close substitutes for each other. FDA's claim does not fully capture consumers' value calculation for luxury goods. The social values - e.g., conspicuous consumption - and the individual values - e.g., of uniqueness -- are diminished when the consumer has less products to match to their values. The market today has many, many varieties of wine and handbags with similar prices and functional value; however, consumers support product diversity and multiple vendors in these markets because of their differences in other consumer values - individual and social. Therefore, the loss of diversity is an implicit price increase that will cause additional current customers to drop out of the premium cigar market.

e. ANALYTICAL APPROACH

Using the assumptions above, we derive a representative estimate of an infrequent, Type I premium cigar smoker's WTP for the experience. We say "representative" because the purpose is to explore the magnitude of FDA's underestimation. The consumer smokes 57 percent of the time alone for the stated benefits of relaxation. The other 43 percent of the type the cigar consumer travels to smoke the cigar socially at an event that has a $100 admission fee. In each scenario, consumers spend some time learning about their cigar choices. Table 8 gives the detailed information of the two scenarios. Weighting these two scenarios by their frequency, this consumer's WTP is approximately $180 per cigar.

However, if this consumer drops out of this premium cigar market due to the regulation increasing the cigar's direct cost or the indirect cost of finding an alternative cigar that meets the consumers' values, the consumer will shift to a substitute activity. Using the assumption above that the consumer values the substitute activity $2 per hour less than cigar smoking, the net loss of consumer surplus per cigar is $70.

Table 9: Willingness-to-Pay (WTP) of Infrequent Cigar Consumers

Characteristics of Infrequent Cigar Consumers	Value and Unit
Number of Cigars Purchased Annually	4 cigars per year
Value of Leisure time	$25.00 per hour
Weighted WTP	$181.3 per cigar
Value of Leisure Time of Substitutes	$23.00 per hour
Weighted WTP of Substitutes	$110.29
Net WTP Loss	**$70 per cigar**
Cigar Smoking as Relaxation	
Pre-Regulation Price of Cigar	$10 per cigar
Time Spent Searching for Cigar	1 hour per cigar
Travel Cost to Obtain Cigar	$21 per cigar
Miles to Cigar Store	15 miles per trip
Travel Cost per Mile	$0.54 per mile
Internet Shipment Cost	$10 per cigar
Cigar Smoking Preparation	0.5 hours
Smoking Cigar	1 hour
Total	**$70**
Total Time	**4 hours**
Cigar Smoking During Social Event	
Pre-Regulation Price of Cigar	$10 per cigar
Time Spent Searching for Cigar	1 hour per cigar
Travel Cost to Event	$16.2 per cigar
Miles Traveled to Event	30 miles per trip
Travel Cost per Mile	$0.54 miles per trip
Admission fee to Event	$100 per event
Event Duration	4 hours per event
Total	**$280**
Total Time	**5.5 hours**

8. RESULTS

a. FUTURE MARKET ESTIMATE

In Section 3, we give our description of the pre-regulatory baseline market conditions. In Table 9, we summarize the cigar market segments and their estimated revenue. We use the sale percentages provided by IPCPR.[50] We multiply these percentages by the total size of the cigar industry ($7 billion). Since sales data is proprietary, our assumptions may not reflect actual sales volumes in these price categories.

Table 10: Cigar Industry Revenue Allocation Across Different Price Segments

Price Range	Price ($)	Sales Percentage	Equivalent Revenue (billions)
$2-$4	$3	5	$0.35
$4-$6	$5	78	$5.46
$6-$10	$6	15	$1.05
Over $10	$10	2	$0.14

To estimate the total number of SKUs for non-premium cigars for each price segment, we multiply the corresponding sales percentage by 2,000 to 4,000. For premium cigars, we assume that the total number of SKUs is 6,000 - 12,000, based on CAA comments.

To be able to understand how price increases due to the regulation will lower cigar demand, we compile reported price elasticity values from the literature. An elasticity of -1.42 means that for a 10 percent price increase, the demand for that cigar will fall in 14 percent. For $2 to $4 cigars, we use the elasticity for small cigars (-1.42). For $4-$6 and $6-$10 cigars we assume that the elasticity corresponds to those of large cigars (-1.50). Both values are based on the estimates quantified by Zheng et al.[51] For premium cigars, we use the elasticity for Cuban cigars (-1.90), estimated by Fetzer.[52]

[50] International Premium Cigar & Pipe Retailers Association, "Premium Tobacconist Member Profile."

[51] Zheng et al., "U.S. Demand for Tobacco Products in a System Framework."

[52] Fetzer, "Partial Equilibrium Modeling of Trade Zeros."

Table 10 summarizes the estimated number of SKUs and price elasticity values for these price ranges:

Table 11: SKU Allocation and Corresponding Price Elasticity Values of Different Cigar Price Ranges

Price Range	Price ($)	SKU Allocation	Elasticity
$2-$4	$3	102 - 204	-1.42
$4-$6	$5	1,592 - 3,184	-1.50
$6-$10	$6	306 - 712	-1.50
Over $10	$10	6,000 - 12,000	-1.90

Using the regulatory cost per SKU, we quantify the total regulatory cost of the rule for each price segment by multiplying the per product cost by the number of SKUs in each category. We then estimate how much the total costs for each category represent in terms of revenue (i.e. divide the total regulatory cost by equivalent revenue).

We compute the total revenue needed in each price segment by adding the total regulatory cost to the equivalent revenue. Then, we divide total revenue needed by the number of SKUs in the price segment to obtain the revenue needed per SKU. We assume that cigar prices will increase to cover the total regulatory cost. We divide both values to obtain the potential price increase (in percentage).

To calculate the decrease in demand, we use the elasticity values and the price increases to quantify the percentage of demand decrease for each price category. Then, we multiply this percentage by the equivalent revenue. Next, we calculate the lost revenue per SKU by dividing the decreased demand value by the number of SKUs in the price category.

Table 11 summarizes the current cost per product and per brand for the rule provisions for which we provided alternative quantified cost estimates:

Table 12: Per-Product and Per-Brand Re-Estimated Costs of Key Rule Provisions

Rule Provision	Current Cost by Brand	Current Cost per Product
Harmful and Potentially Harmful Constituents	$31,352	$4,311
Substantial Equivalence Demonstration	$1,720	$237
Labeling Costs	$139,631	$19,199
Total	$172,703	$23,747

We combine FDA's and the alternative cost estimates for the different requirements for the cigar industry to develop the total compliance cost. These costs are nearly $24,000 per SKU. In a competitive market, firm then try to raise their prices to offset some of these increased production costs. Consumers, in turn, reduce their purchases of the higher-priced cigars according to the price elasticity of demand. Lower consumer purchases then in turn reduced producers' revenue, causing them to either stop selling money-losing products or cease operations. Once producers decide on their compliance strategy, the social costs and economic impact of the rule are known.

Table 12 shows the results of this market dynamic assuming 8,000 SKUs on the market. The lowest-priced cigar market segment has approximately five percent of total sales, or $350 million per year. On average, each of the estimated 100 products would need a price increase of 0.7 percent or $0.02 to adsorb the initial regulatory costs. Consumer demand falls slightly due to this price increase.

The premium market, the last row in Table 12, shows a much more significant effect. There are assumed to be 6,000 SKUs in a market with sales of approximately $175 million. On average, average prices must rise by 46 percent to offset the regulatory costs. This sharp price rise saps consumer demand; consumer demand is estimated to fall from $175 million per year to around $22 million per year. With this sharp fall in demand, very few existing firms could remain in business.

Table 13 presents the same market analysis assuming a market with 16,000 SKUs. Overall compliance costs roughly double. The market impacts in the premium market are even more severe. Based on the reported elasticities, consumers would almost completely shift away from premium cigars to other cigars or other luxury goods.

Therefore, in the premium market, companies would reduce products offered to reduce the compliance costs to identify HPHCs and to seek SE approvals. Table 14 maps out possible scenarios that correspond to different decisions by cigar manufacturers.

The first row in Table 14 gives an important scenario. In this scenario, producers sharply limit the number of cigar products to limit their average revenue losses to three percent. This three percent threshold is the one federal agencies use as a guide to determine if a rulemaking will have a significant effect on small businesses. Federal agencies generally assume that if a regulation costs more than three percent of a small business' revenue, the firm is at high risk of failure. Many cigar

firms meet the U.S. Small Business Administration's classifications as small businesses. Therefore, if premium cigar firms sought to limit their revenue losses to three percent, they would have to lower the number of potential premium cigar products from 6,000 to 130.

If cigar firms maintain a product range of 1,000 SKUs, consumers would decrease purchases so that firms would receive 24 percent less revenue than prior to the regulation. This loss would likely lead to many smaller cigar firms leaving the market and consolidation of the remaining market in a few producers able to manage regulatory costs more efficiently. This type of market consolidation in heavily-regulated industries is apparent in nuclear power plant operators, pharmaceutical firms, and other sectors.

As producers withdraw products from the market, the apparent regulatory compliance costs go down. For example, in the scenario when firms limit their revenue loss on average to three percent, this regulatory compliance strategy reduces the apparent regulatory costs of the rule for premium cigars substantially -- from $149 million in Table 13 to $2 million in Table 14. However, the rulemaking costs only appear to be reduced because the lost consumer surplus is omitted.

Table 13: Total Regulatory Cost for Cigar Market Assuming 8,000 SKUs

Price Range	Mid-Point Price (Range values/2)	Sales Percentage	Equivalent Revenue (from 7 Billion) in million	SKU Allocation (Number of Products)	Adjusted Elasticity Based on Actual Price Increase	Regulatory Cost Per Product (i.e. SKU)	Total Regulatory Cost in million	Total Revenue Needed to Cover Additional Regulatory Costs in million	Revenue Needed Per SKU in million	Cigar Price Increase (+)	Revenue Decrease Due to Lower Demand in millions	New (Reduced) Demand in millions	New Producer Revenue in millions	New Price per SKU
$2-$4	3	5%	$350	102	-0.01	$24,768	$2	$352	$3.52	1%	$3	$350	$350	$3.02
$4-$6	5	78%	$5,432	1,592	-0.01	$24,768	$38	$5,470	$3.52	1%	$57	$5,380	$5,431	$5.04
$6-$8	6	15%	$1,043	306	-0.01	$24,768	$7	$1,050	$3.52	1%	$11	$1,030	$1,043	$6.04
Over $10 (Premium)	10	3%	$175	6,000	-0.87	$24,768	$149	$324	$0.05	46%	$153	$22	$42	$14.60
						Total Regulatory Cost	$197			Total Revenue Decrease	$224			

Table 14: Total Regulatory Cost for Cigar Market Assuming 16,000 SKUs

Price Range	Mid-Point Price (Rados values 2)	Sales Percentage	Equivalent Revenue (from 7 Billion) in million	SKU Allocation (Number of Products)	Adjusted Elasticity Based on Actual Price Increase	Regulatory Cost Per Product (i.e. SKU)	Total Regulatory Costs in million	Total Revenue Needed to Cover Additional Regulatory Costs in million	Revenue Needed Per SKU in million	Cigar Price Increase Pct	Revenue Decrease Due to Lower Demand in millions	New (Reduced) Demand in millions	New Producer Revenue in millions	New Price per SKU
$2-$4	3	5%	$350	204	-0.01	$24,768	$5	$355	$1.7	1%	$5	$340	$350	$3.04
$4-$6	5	78%	$5,432	3,184	-0.01	$24,768	$79	$5,510	$1.7	1%	$79	$5,320	$5,430	$5.07
$6-$8	6	15%	$1,043	612	-0.01	$24,768	$15	$1,060	$1.7	1%	$15	$1,020	$1,043	$6.09
Over $10 (Premium)	10	3%	$175	12,000	-0.87	$24,768	$300	$470	$0.04	63%	$300	$0	$0	$16.30
						Total Regulatory Cost	$400			Total Revenue Decrease	$400			

Table 15: Potential Future Market Size for Premium Cigars

SKUs	Initial Price	Initial Revenue (million)	Regulatory Costs per SKU	Total Regulatory Costs (million)	New Total Revenue Needed (million)	New Revenue Needed per SKU	Price Increase	New Price per Cigar	Reduced Demand Elasticity	New Reduced Demand (million)	Decreased Revenue (million)	Revenue Decrease
130	$10	$175	$24,768	$3	$180	$1,370,000	2%	$10.18	-0.008	$174	-$6.0	-3%
1,000	$10	$175	$24,768	$25	$200	$200,000	12%	$11.24	-0.024	$171	-$41	-24%
2,000	$10	$175	$24,768	$50	$220	$110,000	22%	$12.21	-0.042	$168	-$73	-42%
3,000	$10	$175	$24,768	$74	$250	$80,000	30%	$12.98	-0.057	$165	-$99	-57%
4,000	$10	$175	$24,768	$99	$270	$70,000	36%	$13.61	-0.069	$163	-$120	-69%
5,000	$10	$175	$24,768	$120	$300	$60,000	41%	$14.14	-0.079	$161	-$140	-79%
6,000	$10	$175	$24,768	$150	$320	$54,000	46%	$14.59	-0.087	$160	-$150	-87%

b. ESTIMATES OF CONSUMER WELFARE LOSSES

The possible future markets described in Table 12-13 offer the consumer very different choices than the pre-regulatory market. If producers limit their compliance costs, consumers have much fewer choices of actual and potential products. Based on the pre-regulatory market, consumers value a variety of products and enjoy gaining and sharing information about these products. They will lose a great deal of variety and thus their enjoyment if producers dramatically cut back the number of SKUs. On other hand, if producers raise prices substantially to support more products, our best price elasticity estimate suggests many consumers will turn to non-cigar products. Cigar consumption will fall substantially.

In each of these cases, the social cost of the rule includes consumer utility not directly traded in the cigar market. As discussed above, the price consumers are willing to pay for the experience is much larger than the price of the cigar itself. When prices rise in a relatively free market due to regulation, the social cost is both the real resources necessary for compliance as well as the deadweight loss, the loss in consumer utility as they drop out of the market in response to the price increase.

We could estimate how much consumers value variety by estimating the cross-elasticities of price and of substitutions between different premium cigar products. We did not find readily-available estimates of product cross-elasticities in the publicly-available literature. Estimating these elasticities from market sales data is beyond the scope of this analysis.

In the absence of market data, we consider several approaches to estimate consumer welfare loss that will arise once the regulation is fully effective. First, we consider the traditional scenario where the cigar's market price fully includes all of the consumer's utility for the product. In free markets, the market's supply and price reflect the maximization of consumer utility subject to the production costs to produce it. Consumers will pay more for the product if the production cost is less than the cost of the physical resources needed to make the product; the cigar market is a good example where retail prices are substantially above production costs. However, if consumers bundle spending together as part of the cigar experience, just using the cigar price will underestimate the consumer's welfare to overcome this limitation, we also use the estimated consumer surplus loss of $70 per cigar from Section 7.

Second, we will assume that consumers' utility is spread equally across all of the pre-regulation SKUs. This scenario represents a situation where consumers put a high value on the discovery of different products as a key part of their cigar experience. If actual or potential products are removed from the market, consumer lose utility each time a product is withdrawn. As with wine markets, some consumers enjoy exploring the thousands and thousands of different vintages, bottlers, and regions. However, some consumers value the social interaction as part of the cigar experience; they may value that more than the specific cigar they consume.

For the traditional scenario, we first estimate the change in the number of cigars sold under some of the future market descriptions given above. In Table 15, we estimate the number of cigars sold based on different product offering decisions by cigar firms. If firms only seek FDA approval to offer 3,000 of the current number of varieties of premium cigars, consumer demand falls to $76 million per year. Using the average, post-regulation premium cigar price of $12.98, the number of cigars sold

each year is more than 5.8 million. If producers curtail product choice more dramatically to 1,000 SKUs, nearly 12 million cigars will be sold.[53]

Table 16: Assumed Number of Premium Cigar SKUs Remaining in the Market

Category	Assumed Number of Premium Cigar SKUs Remaining in Market		
	3,000 SKUs	2,000 SKUs	1,000 SKUs
Regulatory Compliance Costs (million)	$74	$50	$25
Price Increase	$2.98	$3.53	$1.98
New Cigar Price	$12.98	$12.21	$11.24
New Reduced Demand (million)	$76	$102	$134
Number of Cigars Sold	5,800,000	8,300,000	11,900,000

Assuming the demand curve is linear, we can estimate the deadweight loss from the increases in price and decrease in quantity of cigars sold from the regulation. Table 16 gives this estimate for three post-regulation scenarios of 1,000, 2,000, and 3,000 SKUs remaining on the market.

Table 17: Social Cost from Consumer Welfare Losses in Premium Cigar Market

Assuming Welfare Loss in Price

Consumer Welfare Loss ($ millions)	Assumed Number of Premium Cigar SKUs Remaining in Market		
	3,000 SKUs	2,000 SKUs	1,000 SKUs
Cigar Price Only	17	10	3.5
WTP Estimate	410	320	200

[53] In the 1,000 SKU scenario, the regulatory compliance costs are $25 million. Since FDA approval is only sought for 1,000 SKUs, lower compliance costs lead to lower price increases. As a result, the demand in this scenario ($134 million) and the number of cigars sold ($11.9 million) are higher than for other scenarios shown in Table 15.

These social costs likely underestimate the actual social costs for the reasons discussed above. The linear demand curve assumption also likely underestimates the social cost. The demand curve may not be linear for such a substantial increase in price and reduction in quantity. If it has a traditional convex shape to the origin, the consumer welfare loss would be greater than this linear estimate.

For the second scenario, we estimate the total consumer welfare for premium cigars. It is the average willingness to pay ($158) multiplied by the number of cigars sold (assumed to be 17.5 million per year) in the pre-regulation market. We then divide this total welfare by the assumed number of premium cigar SKUs in the pre-regulation market, 6,000 or 12,000. We then have the average welfare value consumers gain from each unique product in the marketplace.

In Table 17, the estimated lost consumer surplus for each post-market product volume is shown. If producers sharply curtail the number of products to minimize their compliance cost to three percent of revenue, almost all consumer welfare is eliminated. With only 130 products, the premium market would more resemble the other mass market segments of the market. It would be much harder to distinguish the remaining products as premium, luxury brands that can satisfy consumers' values for luxury goods. Consumers who gain enjoyment from exploring new products may quickly become bored with only 130 varieties. Due to this significant loss, consumers costs for having 130 cigar varieties in the market would be $2,700 million. This consumer loss exceeds significantly the size of the $175 million premium cigar market. At the other end of the spectrum, if producer pay the compliance costs to maintain 6,000 SKUs, consumers suffer no welfare loss due to the regulation.

The second scenario (Table 17 - Lost WTP for market of 12,000 premium SKUs) --- where consumers value product diversity - gives much higher estimates of consumer welfare loss. We expect that the likely loss in consumer welfare will be in between these estimates but is likely greater than $100 million per year.

Table 18: Consumer Costs of the Rule

SKUs	Lost WTP For Market of 6,000 Premium SKUs ($ million)	Lost WTP For Market of 12,000 Premium SKUs ($ million)
130	2,700	2,700
1,000	2,300	2,500
2,000	1,800	2,300
3,000	1,400	2,100
4,000	900	1,800
5,000	500	1,600

SKUs	Lost WTP For Market of 6,000 Premium SKUs ($ million)	Lost WTP For Market of 12,000 Premium SKUs ($ million)
6,000	0[54]	1,400

[54] Lost WTP for 6,000 SKUs in this scenario is zero, as producers pay the compliance costs to maintain the 6,000 SKUs in the market. In this scenario, consumers are unaffected.

9. CONCLUSION

The regulatory compliance costs for the non-premium market is about $50-$100 million for this initial compliance period. This value underestimates the full costs for this market since the ongoing costs are omitted as well as the loss of consumer surplus.

The regulatory costs for the premium market depend on the market choices of firms and of consumers. If firms reduce product offerings from 6,000 to 1,000, the combined consumer surplus loss is between $3.5 million (see Table 16) and 2,300 million per year (see Table 17). The initial compliance costs are $25 million (See Table 15).

Table 19: Summary of the Rule's Initial Compliance Costs and Consumer Surplus Loss

Cigar Category	Initial Regulatory Compliance Costs (million)	Consumer Surplus Loss
Non-Premium	$50-$100	Not estimated
Premium	$150-$300	$3.5 to $2,300 million per year[55]

These values are not directly comparable to FDA's cost estimates. FDA presented its values as present value estimates at different discount rates over a 20-year time horizon. The estimates presented in this analysis have different time periods. The direct regulatory compliance costs producers must spend over the next few years up to the final compliance deadlines. Some costs such as the registration, substantial equivalence, and other product-related requirements are on-going. The lost consumer surplus is an annual loss. As described in the HHS guidance, there is some evidence that this consumer loss will decline over time as other substitutes become available and consumers "forget" their past enjoyment of the experience.

Therefore, to convert these estimates to present value numbers equivalent to FDA's metrics, we would need to make additional assumptions. However, it is clear that for the range of likely future market scenarios for the premium cigar market and given the estimated consumer welfare loss in the other cigar market segments, the likely social costs of this rulemaking are much larger than FDA's estimate. In addition, the likely scenarios for the future premium cigar market all are likely to have a significant effect on a substantial number of small entities.

[55] Assuming a reduction of 5,000 SKUs

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April 3, 2019

The Honorable Marco Rubio, Member
U.S. Senate
284 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Rubio:

On behalf of Cigar Rights of America, we would like to thank you for conducting a hearing this week on the issue of federal regulation of premium cigars, and the devastating impact they will have on small businesses in Florida and across the nation. You have been a stalwart supporter of legislation to exempt premium cigars from FDA regulatory authority since the 112th session of Congress, and as this issue has advanced and become more critical for the industry, your recognition, through this hearing, will bring newfound attention to the role this industry has in Florida, throughout the nation, and indeed, within this hemisphere.

We simply want to highlight, for the purposes of this hearing in Ybor City, some of the major issues surrounding regulations enacted by the U.S. Food & Drug Administration. These regulations present serious economic, logistical, and legal challenges, and trigger issues with national security implications, while failing to impact the public health intent of the Family Smoking Prevention and Tobacco Control Act.

First, the U.S. Food & Drug Administration failed to conduct a vigorous economic impact analysis. Research presented by Mangum Economics, using only standard issued government data, clearly denotes over 25,000 jobs at risk of elimination due to the regulatory regime advanced by the FDA. While the retail jobs at risk of elimination span the nation, the manufacturing, logistics, corporate headquarters, and distribution channel jobs are concentrated in Florida. The study also notes the adverse impact of regulation on the cigar tobacco agricultural community that predominately exists in Pennsylvania, Connecticut and now Florida. The study further highlights how the cost of cigar regulation falls disproportionately on the premium handmade sector, with the cost of compliance being 100% of their profit margin. A copy of this analysis is attached for the record, and review by the committee.

It is also noteworthy, that of the estimated $70 million in "user fees" the industry is compelled to remit to the FDA annually, the vast majority of that will be siphoned out of the Florida economy (article attached.)

The U.S. Small Business Administration warned of this in a June 11, 2014 letter to former FDA Commissioner, Margaret Hamburg, stating that the SBA Office of Advocacy "is concerned that the FDA's proposed rule and the Initial Regulatory Flexibility Analysis (IRFA) lack essential information needed...the IRFA does not adequately describe the costs of the proposed rule on small entities, and the IRFA does not set forth, consider, and discuss significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities." A copy of the SBA letter is attached for the record.

The FDA states that regulations should be designed based upon where products fall on "the continuum of risk," yet, many of the regulations advanced by the agency treat premium handmade cigars worse than cigarettes and other tobacco products, which Congress actually directed the agency to regulate. The warning label requirements, exceeding 30% of an artisan cigar box, for example, was noted in the industry litigation in opposition to the rule. It took U.S. District Judge Amit Mehta to note in his opinion to stay the regulation saying, "this court cannot let pass without comment what it "deems" to be a grossly unfair exercise of agency authority" noting further that the agency actions. "smack of basic unfairness." This threat, however, of excessive warning label requirements loom over the industry's head.

Further threatening this small artisan industry are product testing requirements that were recently delayed by the agency. The proposed regimen would mandate testing of premium handmade cigars in a manner impossible, either monetarily or logistically, that is unprecedented, for an all natural product which has no additives other than all natural dark air cured tobacco, water, and a small amount of vegetable gum. Premium hand-rolled cigars contain no chemical additives or nicotine manipulation. Only soil, sun, and aged over time and blended and rolled by skilled craftsmen who spend years perfecting their trade. FDA has to date failed to provide clear guidance concerning testing requirements creating significant uncertainty for producers of products that take 3-5 years to be created and reach store shelves.

There also exist hemispheric economic and security concerns. Premium handmade cigars sold in the United States are predominately produced in the Dominican Republic, Honduras and Nicaragua. This economically and politically fragile region relies on premium handmade cigars as a foundation of their economic stability. Over 300,000 jobs directly associated the premium cigars are within this region. The supply chain broadens that region further.

The Honorable Jorge Alberto Milla Reyes, former Ambassador to the United States for Honduras stated, "There are, indeed, international trade and economic implications with regulating premium cigars from Honduras, and throughout Latin America. The government of Honduras, values the investment and source of employment provided by the premium cigar industry, and knows well how it provides for over 35,000 families in Honduras and 300,000 in the region. We cannot underestimate how this contributes to stability, especially at this time of concern over issues such as immigration and security."

Cigar Rights of America has raised the local concern of the impact these regulations can have right here, in Ybor City. In addition to the historic J.C. Newman factory with which you are familiar, there are numerous small business artisan handmade cigar producers, close by on 7thAvenue in Ybor City.

Their ability to comply with onerous regulations is questionable, but their role in the historic cultural fabric of this community, is not. Ybor City is a nationally designated historic district, designated in large part due to its history with the cigar industry. We believe the U.S. Department of the Interior should be consulted on the impact of these regulations on this district, and we have raised that concern to the Trump Administration.

In a related context, we believe the U.S. Department of Agriculture should be advised and utilized in this matter, due to the potential adverse economic consequences for American farmers, predominately in Pennsylvania, Connecticut and now Florida (as noted in the attached economic impact analysis.) These are the last remnants of cigar tobacco farming in this nation, and it is a prized commodity within the industry. The threat these regulations pose to the agricultural sector has gone ignored by the agency, and Cigar Rights of American has also brought this to the attention of the Trump Administration.

On July 25, 2018, Cigar Rights of America filed a report with the FDA in response to the agency initiating a public comment purely on issues surrounding premium cigars. We appreciate this recognition that the product deserves distinct consideration, as opposed to being lumped in with e-cigarettes and vape products as they were in the initial rule-making process. CRA submitted over 500 pages of analysis that clearly makes the case for a reformed approach to regulation, and in fact, makes the case for exemption. The studies and data, some of which is derived from such sources as the New England Journal of Medicine, American Medical Association and Centers for Disease Control, coupled with analysis addressing consumer demographic, patterns of usage, as well as inhalation,, addiction, mortality, and youth access data, all of which clearly indicated the need for premium cigar regulatory reform and/or exemption. It's time for an objective recognition that this report is a sound and factual basis for a new approach to this rule.

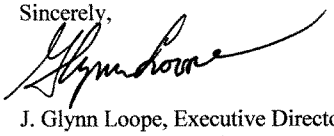
Given your leadership on this issue, and for the State of Florida, it is also worthy to note that the following (attached) have raised their concerns on the regional economic impact of these regulations, as well as impact on the historic and cultural role the industry has in the community:

- Office of the Mayor of Tampa
- Office of the Mayor for the City of Miami
- Greater Tampa Chamber of Commerce
- Ybor City Chamber of Commerce
- Port of Tampa

Since the 112th session of congress, over 289 members of the U.S. House of Representatives and twenty-six members of the U.S. Senate has sponsored legislation to exempt premium cigars from FDA regulatory authority. Seventy-two of these members voted for the original Tobacco Control Act. They knew, and those on your S. 9, and now H.R. 1854, know, that premium handmade cigars do not carry the addiction, inhalation, mortality and youth access issues, that were the very reason congress passed the act. For that reason alone, regulatory reform for premium cigars is critical for the industry.

Again, thank you for the opportunity to submit this statement, and please do not hesitate to contact us with any questions, or for additional information.

Sincerely,



J. Glynn Loope, Executive Director
Cigar Rights of America

Cigar Rights of America
300 New Jersey Avenue, N.W.
Washington, D.C. 20001

CITY OF TAMPA

Bob Buckhorn
Mayor

January 9, 2014

Dr. Margaret A. Hamburg, Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

It has come to my attention that the U.S. Food & Drug Administration - Center for Tobacco Products, is advancing regulation of cigars, as a component of its overall regulation of tobacco.

Premium cigars, it should be noted, have a historic, strong and vibrant role in the greater Tampa Bay economy, and many of the regulations that could be imposed on the industry would have a most adverse impact on these businesses within the Tampa community.

Tampa is the home for such staples of the industry, such as J.C. Newman Cigar Company, A. Fuente Cigar Company, Thompson Cigar Company, Davidoff U.S.A., Altadis U.S.A., and over seventy-five local premium cigar retail establishments, many of which are traditional family owned small businesses.

While I understand and appreciate the original intent of The Tobacco Control Act to address youth access to tobacco and chemical addiction, premium hand-made cigars do not meet this threshold. Premium cigars are enjoyed by discerning adults; are traditionally beyond the price-point for youth; are used in a celebratory or 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.

I hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Tampa.

Sincerely,

Bob Buckhorn

City of Miami, Florida

TOMÁS P. REGALADO
MAYOR

3500 PAN AMERICAN DRIVE
MIAMI, FLORIDA 33133
(305) 250-5300
FAX (305) 854-4001

January 23, 2015

The Honorable Sylvia Mathews Burwell
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Secretary Mathews-Burwell:

As you are aware, the U.S. Food & Drug Administration issued a Deeming Regulation for cigars and other tobacco products on April 25, 2014. Although the Public Comment period is now closed, we feel that for the City of Miami, there are numerous issues of economic significance that should be taken into account, as this regulatory proposal is under review.

The State of Florida is the headquarters for over forty corporations in the premium cigar industry, in Tampa, Miami and Ft. Lauderdale, with Miami hosting the most corporate offices for the industry. Florida is home to at least 232 small businesses reliant upon the sale of premium cigars, with 119 in Miami with premium cigar accounts; and Miami is the base of operations for the logistics surrounding the distribution of cigars entering from Latin America, as well as raw leaf for domestic cigar production, through the Ports of Miami, Tampa and Ft. Lauderdale being utilized by the industry. Shipping, trucking, bonded storage and related operations are all based in Miami, to support the premium cigar industry.

Also specific to the Miami economy, the Little Havana community is home to numerous boutique premium cigar manufacturers. These facilities would be subject to the same federal regulations as a multinational conglomerate cigar manufacturer, and it would be impossible, for these local businesses to survive this proposed type of federal regulation.

Florida, and the greater Miami community specifically, also serves as host to dozens of premium cigar themed festivals that bring thousands of travelers to the region each year. This impact on local and state tourism should also be taken into consideration.

I believe that the proposed Deeming Regulation for premium cigars needs a comprehensive economic impact analysis addressing how such regulations could affect these facets of the Miami economy, before entering any Final Rule process, while also believing that the most serious consideration should be given to the "Option 2" path to exempting premium cigars from these proposed regulations, at all.

Please advise our office as to information that may be needed to initiate such an economic assessment, as we can facilitate an exchange with the affected business interests in the headquarters operations, distribution, retail and agricultural sectors in Miami that will be most directly impacted by any approach to regulating premium cigars.

Your attention to this matter is appreciated.

Sincerely,

Tomás Regalado
Mayor

cc: The White House Office of Management & Budget
Attention: Mr. Shaun Donovan
Office of Information & Regulatory Affairs
Attention: Mr. Howard Shelanski
725 17th Street, N.W.
Washington, D.C. 20503

GREATER TAMPA CHAMBER OF COMMERCE

February 21, 2014

Dr. Margaret A. Hamburg
Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg,

The Greater Tampa Chamber of Commerce urges the Food and Drug Administration (FDA) to cease its impending regulation of premium cigars under the Tobacco Control Act. We believe this regulation constitutes overly-burdensome restraint on this industry.

FDA regulation of premium cigars would harm a legacy industry for the Tampa Bay area. Over seventy-five local small businesses, many of which are family owned, provide artisan cigars to customers. Some of these companies have been in business for over one hundred years. JC Newman Company, located in the historic Ybor district of Tampa, is the country's oldest family-owned premium cigar maker. Many Tampa Bay families immigrated to the United States and got their start in this county working in Ybor cigar factories. FDA regulation would endanger these companies survival and would threaten the existence of a piece of our local history.

Changes to the ways in which our local cigar companies operate, including the way they can display their products within their retail stores, alteration of the flavor of their tobacco because of new irrigation requirements, and delays, perhaps years-long, before products can be sold constitute overly-burdensome regulation. The Chamber and its 1,200 business members ask that you end attempts to regulate the premium cigar industry.

Sincerely,

Bob Rohrlack, CCE, CEcD
President and CEO

www.tampachamber.com

PO Box 420, Tampa, FL 33601 • 201 North Franklin Street, Suite 201, Tampa, FL 33602-5846 • 813.228.7777 • (f) 813.223.7899

YBOR CHAMBER

February 20, 2014

Dr. Margaret A. Hamburg, Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As we understand it, the U.S. Food & Drug Administration – Center for Tobacco Products is undertaking additional regulation of cigars as an element of its overall regulation of tobacco.

Premium cigars have played a key cultural and economic role in Ybor City since April 13, 1886. We were founded as Florida's first industrial town around the "cigar industry." Additional regulation of this fragile "home grown" business could have serious impacts on the hand-rolling cigar shops that dot our National Historic Landmark District.

As the once "cigar capital" of the world, Tampa Bay is home today to key companies in the industry including: A. Fuente Cigar Company, J.C. Newman Cigar Company, Davidoff USA, Altadis USA, Thompson Cigar Company and over 75 local premium cigar retailers.

While we appreciate the original intent of The Tobacco Control Act to address access of young people to tobacco and chemical addiction, premium cigars do not meet this threshold. Premium cigars are enjoyed primarily by adults; are usually beyond the price-point for youth; are used in a celebratory or infrequent manner; and are produced as an artisanal product that appeals to a specialized market, rather than to the general public.

I would hope that you would take the position of our Board of Directors into consideration as you more forward. Please consider the impact that further regulation could have on our local cigar bars and overall heritage tourism within Ybor City and Tampa.

Sincerely,

Thomas P. Keating

1800 E. 9th Avenue, Tampa, Florida 33605
813-248-3712 • fax 813-247-1764
www.ybor.org • email info@ybor.org

TAMPA BAY BAY

August 6, 2014

Division of Dockets Management
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG3

Dear Commissioner Hamburg:

We have become aware that the U.S. Food and Drug Administration – Center for Tobacco Products, is advancing regulation of premium cigars as a component of its overall regulation of tobacco.

Premium cigars have a strong connection to Tampa and to our regional economy. Our community and our port have rich, historical ties to this industry dating back over 100 years. Today, over seventy-five local small businesses provide artisan cigars to customers.

While we certainly understand and appreciate the original intent of the Tobacco Control Act to address youth access to tobacco and chemical addiction, premium cigars do not meet this threshold. FDA regulation would endanger a legacy industry and would threaten the existence of a piece of local history.

We respectfully request that you refrain from regulatory actions that can adversely impact local and regional existing businesses such as the legacy cigar interests of Tampa. Thank you for your consideration.

Sincerely,

A. Paul Anderson

A. Paul Anderson,
President and CEO

1101 Channelside Drive Tampa, Florida 33602-3612 P: 813.905.7678 800.741.2297 F: 813.905.5109

CRA CIGAR RIGHTS OF AMERICA

300 New Jersey Avenue | Suite 900
Washington, DC 20001
Phone: 202.469.3444 Fax: 800.460.6207
E-Mail: info@cigarrights.org Web: www.cigarrights.org

July 16, 2018

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6189

Dear Sir or Madam:

Cigar Rights of America ("CRA") submits these comments in response to the Advance Notice of Proposed Rulemaking ("ANPRM") issued by the U.S. Food and Drug Administration (the "FDA") regarding the development of a tobacco product standard for the nicotine level of cigarettes.[1] Among other topics, the FDA requests comments and information on the scope of a prospective nicotine-level standard, specifically naming premium cigars as a class of tobacco products potentially meriting exclusion.[2] CRA commends the FDA for recognizing that premium cigars are made and used differently than all other tobacco products and believes that those differences make a nicotine-level standard for premium cigars both unnecessary and infeasible. To that end, the agency should consider, in addition to the comments and data submitted in response to this rulemaking docket, information submitted on the parallel rulemaking docket addressing premium cigars. CRA urges the FDA not to extend any tobacco product standard for nicotine levels to premium cigars.

CRA is a non-profit association that serves as a voice of premium cigar manufacturers and consumers in the United States on matters of legislative and regulatory concern, with a membership that spans all 50 states. CRA members include over 60 diverse artisan producers of handmade premium cigars. CRA's membership also reaches the entire spectrum of the supply chain—distributors, growers, mail-order houses, logistics, and associated supporting enterprises—as well as consumers of premium cigars. Overall, CRA estimates that there are nearly 35,000 jobs tied to the premium cigar and premium tobacco retail industry in the United States.

I. Statutory and Regulatory Background

Section 907 of the Family Smoking Prevention and Tobacco Control Act (the "TCA") authorizes the FDA to issue a tobacco product standard *if* the Secretary of the Department of Health and Human Services (the "Secretary") makes an express finding that such a standard "is appropriate for the protection of public health."[3] In making this finding, the Secretary must consider "scientific evidence" on three topics: (1) "the risks and benefits to the population as a

[1] Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (Mar. 16, 2018).
[2] *Id.* at 11,826.
[3] 21 U.S.C. § 387g(a)(3)(A).

whole, including users and nonusers of tobacco products, of the proposed standard"; (2) "the increased or decreased likelihood that existing users of tobacco products will stop using such products"; and (3) "the increased or decreased likelihood that those who do not use tobacco products will start using such products."

In this ANPRM, the FDA seeks information to "develop[] a tobacco product standard to set the maximum nicotine level for cigarettes."[4] Consistent with its acknowledgment that combustible cigarettes reside at the most dangerous end of the "continuum of risk,"[5] the FDA appropriately has focused this ANPRM on cigarettes, with only peripheral attention to other tobacco products. Indeed, the FDA's ultimate objective is to "[g]reatly reduc[e] or eliminat[e] the addictiveness of cigarettes,"[6] which the agency has characterized as "one of our nation's greatest public health challenges."[7] To the extent the agency is considering extending the nicotine standard to other tobacco products, its stated concerns motivating such an extension are migration of cigarette users to other tobacco products and dual usage of cigarettes and another tobacco product.[8] Properly defined, premium cigars implicate neither issue: The scientific evidence is clear that premium cigars are not used to feed a nicotine addiction or otherwise for nicotine delivery or as complements to cigarettes. Accordingly, excluding premium cigars from any nicotine level standard would not lead to any weakening of a nicotine standard for cigarettes through the potential migration or dual use mechanisms identified by the agency.

II. Premium Cigars Should Be Excluded from Any Nicotine Level Standard

Premium cigars, by their very nature, are not cigarette substitutes. They contain only tobacco leaf and an adhesive, they are made by hand rather than through mechanization, and they cost far more and are used far less frequently than other tobacco products.

A. Definition of Premium Cigars

When weighing a regulatory exemption for premium cigars, the FDA identified seven essential features of the definition of a premium cigar, which CRA endorses: (1) it is wrapped in whole tobacco leaf; (2) it contains a 100 percent leaf tobacco binder; (3) it contains primarily long filler tobacco; (4) it is made by combining manually the wrapper, filler, and binder; (5) it has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) it does not contain an additive that is a characterizing flavor other than tobacco; and (7) it weighs more than 6 pounds per 1,000 units.[9] CRA will address the proper definition of premium cigars in forthcoming comments for the FDA's ANPRM on the regulation of premium cigars (the "Premium Cigar

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[4] 83 Fed. Reg. at 11,818.

[5] *See* Press Release, FDA, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm ("A key piece of the FDA's approach is demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.").

[6] 83 Fed. Reg. at 11,818.

[7] *Id.* at 11,825.

[8] *Id.*

[9] Proposed Rule, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142, 23,150 (Apr. 25, 2014).

ANPRM Comments").[10] In those comments, we will urge the FDA to omit an eighth factor: a minimum retail price requirement, which we believe will be practically unadministrable. It would be very difficult to create a *manufacturing* standard based on the price at which a product is sold by a *retail* establishment. In any event, the required method of construction for premium cigars—that they are made entirely by hand—ensures that they can neither be produced nor profitably sold cheaply. It is worth noting that FDA staff, when publishing the below-referenced study of premium cigars in *Nicotine & Tobacco Research*, did not use the FDA's $10 price target as a cut off and studied cigars that, on average, sold for $2 or more.[11] Premium cigars meeting the above definition are not candidates for migration or dual use, or for youth initiation or use, as recent scientific studies confirm, and therefore should be excluded from any nicotine-level standard.

Further, this definition—and, in particular, the requirement that each cigar be made by hand—effectively precludes the manufacturers of other types of cigars from rebranding their products as premium cigars. The restrictions on ingredients and the requirement of manual production together act as a significant barrier to entry. There is therefore virtually no risk that a nicotine-level standard excluding premium cigars would create a regulatory loophole and expose the public to higher risk tobacco products.

B. Premium Cigar Consumer Demographics and Patterns of Use

Premium cigars are used primarily by older, higher educated, and wealthier adults. Data from the Population Assessment of Tobacco and Health Study (the "PATH Study"), a nationally representative, longitudinal cohort study of more than 45,000 adults and youth in the United States from 2013 to 2016, provide valuable insights into the demographic profile of the typical premium cigar user. According to the *Nicotine & Tobacco Research* study, which examined PATH Wave 1 data (2013–14), 57% of adult premium cigar consumers were over the age of 35.[12] In addition, 73.8% of that group at least had completed some college or earned an associate degree (including 38.9% with a college degree or higher), and 62.7% of that group had a household income exceeding 200% of the federal poverty level—both figures considerably higher than for adult users of non-premium cigars, cigarillos, filtered cigars, and cigarettes.[13] Another recent study in the *New England Journal of Medicine*, also using PATH Wave 1 data, found that only 2.3% of youths had *ever* used a "traditional cigar"—a category that includes both premium and non-premium cigars—and that the proportion of youth engaged in "frequent" or "daily" use of traditional cigars was so small that it was indistinguishable from zero.[14]

NERA Economic Consulting ("NERA") has independently reviewed and analyzed the PATH data, and not only has confirmed the findings of these studies with respect to Wave 1, but also has determined that Wave 2 (2014–15) and Wave 3 (2015–16) data paint a similar

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[10] Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018).

[11] Catherine G. Corey et al., *U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014*, Nicotine & Tobacco Res., Sept. 15, 2017, at 1, supp. tbl.A (Ex. 1).

[12] *Id.* at 4 tbl.1.

[13] *Id.*

[14] Karin A. Kasza et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 376 N. Eng. J. Med. 342, supp. app. tbls.S3, S4 (2017) (Ex. 2).

demographic picture.[15] NERA's results, which will be laid out in greater detail in the Premium Cigar ANPRM Comments, indicate that approximately 57–67% of adult premium cigar consumers were over the age of 35, approximately 39-50% of adult premium cigar consumers have a college degree or higher, and approximately 65% of adult premium cigar consumers had a household income exceeding 200% of the federal poverty level (including 36–44% with household incomes exceeding $100,000).

Premium cigars also are used very infrequently and in a manner inconsistent with use to feed nicotine addiction or otherwise as a nicotine delivery method. According to the *Nicotine & Tobacco Research* study, again analyzing PATH data, the median consumer of premium cigars used those products on 1.7 of the past 30 days and smoked 0.1 cigars per day.[16] Only 6.7% of premium cigar consumers used those products daily.[17] These figures stand in stark contrast to cigarettes: The median adult cigarette user smoked 29.4 days in the past month, including 10.1 cigarettes daily, and 79.5% of adult cigarette users engaged in daily use.[18] NERA's analysis underscores the infrequency of premium cigar use. Across all three PATH waves, the median adult consumer of premium cigars used those products on 1.3–1.7 of the past 30 days, and only 3.9–7.5% of adult premium cigar consumers used those products daily.[19] Such low frequency of use of premium cigars simply is not consistent with using the products to satisfy a nicotine addiction or otherwise to deliver nicotine. And, as the agency observes repeatedly in the ANPRM, nicotine delivery appears to drive the frequency of tobacco use.[20]

The data further show that premium cigar consumers are not using the products in any meaningful numbers to supplement cigarette use. In each PATH wave, the median premium cigar consumer smoked cigarettes on *zero* days in the past 30 days, compared with 29.2 days for the median filtered cigar consumer, 29.0 days for the median non-premium cigar consumer, and 19.9 days for the median cigarillo consumer (in Wave 1).[21] Even those relatively few consumers of premium cigars who smoked cigarettes with any meaningful frequency consumed no more premium cigars than the median premium cigar user: Both used premium cigars on fewer than 2 days per month.[22]

These data demonstrate that premium cigars are not being used with a frequency consistent with use as a nicotine delivery system. Rather, the data indicate that the demographics

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[15] *See* NERA Letter (July 16, 2018) (Ex. 3). NERA used the same definition of "premium cigar" as in the *Nicotine & Tobacco Research* study, with certain limited refinements to correct apparent misclassifications by that study's authors. NERA's methodology receives further elaboration in NERA's Expert Report accompanying the Premium Cigar ANPRM Comments.

[16] Corey et al., *supra* note 11, at 5 tbl.2.

[17] *Id.*

[18] *Id.*

[19] NERA Letter at 2-3.

[20] *See, e.g.*, 83 Fed. Reg. at 11,823 ("Tobacco products are addictive, primarily due to the presence of nicotine."); *id.* at 11,824 ("The addiction potential of a nicotine delivery system varies as a function of its total nicotine dosing capability, the speed at which it can deliver nicotine, the palatability and sensory characteristics of the system, how easy it is for the user to extract nicotine, and the cost of the delivery system."); *id.* ("The amount of nicotine delivered and the means through which it is delivered can either reduce or enhance a product's potential for abuse and physiological effects."); *id.* ("Quicker delivery, higher rate of absorption, and higher resulting concentration of nicotine increase the potential for addiction.").

[21] NERA Letter at 3.

[22] *Id.* at 3-4.

and use patterns of premium cigar consumers are dramatically different from those of consumers of other tobacco products. Rather than as nicotine delivery devices, premium cigars are being used as luxury goods reserved for occasional indulgence primarily by older and wealthier adults. Moreover, the defining features of premium cigars—especially their all-natural and handmade character, which raise their cost—make them extraordinarily unlikely candidates for migration following the implementation of a nicotine-level standard for cigarettes. In view of these data, the FDA cannot make the statutory findings necessary to extend to premium cigars a tobacco product standard addressing nicotine levels, *see supra* Section I, and the agency should exclude premium cigars as defined in Section II.A from any such standard.

III. Premium Cigars Cannot Feasibly Comply with Any Nicotine Level Standard

In addition, a nicotine standard for premium cigars would be entirely infeasible to implement. By definition, premium cigars contain only tobacco leaf (grown, cured, and aged naturally) and a small amount of vegetable adhesive. In addition, the tobacco leaf in each premium cigar is selected by a master tobacconist to achieve a specific sensory profile, and consumers seek out premium cigars for these very qualities. CRA is not aware of any means of reducing nicotine levels in natural tobacco leaf that would preserve the integrity of the premium cigar manufacturing process. Chemical extraction and genetic engineering are fundamentally incompatible with the concept of a premium cigar.[23] These measures might make sense for cigarettes, which historically have been allegedly chemically engineered to maximize addictiveness and which roll off of mechanized assembly lines millions at a time, but they simply cannot be applied to natural products that have been made the same way for centuries. In short, it is not only unnecessary, but also infeasible to impose a nicotine-level standard on premium cigars.

IV. Conclusion

When announcing the FDA's new, comprehensive plan for tobacco regulation, Commissioner Gottlieb trained the agency's attention squarely on cigarettes: "The overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes—the only legal consumer product that, when used as intended, will kill half of all long-term users."[24] The agency should act consistently with Commissioner Gottlieb's vision and limit any tobacco product standard for nicotine levels to cigarettes. At the very least, the agency should exclude premium cigars from any such standard, as these luxury goods present practically no risk of tobacco initiation, migration, or dual use, and cannot, by their very nature, comply.

CRA appreciates the opportunity to provide comments on this important matter.

Respectfully submitted,

J. Glynn Loope

J. Glynn Loope
Executive Director, Cigar Rights of America

[23] *See id.* at 11,831–32.
[24] Press Release, *supra* note 5.

EXHIBIT 1

Nicotine & Tobacco Research, 2017, 1–10
doi:10.1093/ntr/ntx209
Original investigation
Received April 26, 2017; Editorial Decision September 8, 2017; Accepted September 12, 2017
Advance Access publication September 15, 2017

Original investigation

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

Catherine G. Corey MSPH[1], Enver Holder-Hayes MPH[1], Anh B. Nguyen PhD[1], Cristine D. Delnevo PhD[2], Brian L. Rostron PhD[1], Maansi Bansal-Travers PhD[3], Heather L. Kimmel PhD[4], Amber Koblitz PhD[1], Elizabeth Lambert MSc[4], Jennifer L. Pearson PhD[5], Eva Sharma PhD[6], Cindy Tworek PhD[1], Andrew J. Hyland PhD[3], Kevin P. Conway PhD[4], Bridget K. Ambrose PhD[1], Nicolette Borek PhD[1]

[1]Center for Tobacco Products, US Food and Drug Administration, Silver Spring, MD; [2]Center for Tobacco Studies, School of Public Health, Rutgers University, Piscataway, NJ; [3]Department of Health Behavior, Roswell Park Cancer Institute, Buffalo, NY; [4]National Institute on Drug Abuse, National Institutes of Health, Bethesda, MD; [5]Schroeder Institute for Tobacco Research and Policy Studies, Truth Initiative, Washington, DC; [6]Westat, Rockville, MD

Corresponding Author: Catherine G. Corey, MSPH, Office of Science, Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA. Telephone: 301-796-7396; Fax: 301-595-1138; E-mail: catherine.corey@fda.hhs.gov

Abstract

Introduction: The US cigar market is diverse, yet until recently most research studies and tobacco surveillance systems have not reported behavioral and related outcomes by cigar type.
Methods: The 2013–2014 Population Assessment of Tobacco and Health Study collected data separately for filtered cigars (FCs), cigarillos, and traditional cigars, which were further distinguished as premium or nonpremium. Descriptive statistics for adult established current smokers of each cigar type and cigarettes were calculated for demographic characteristics, tobacco use patterns, purchasing behaviors and reasons for use. Adjusted prevalence ratios (APRs) using a marginal predictions approach with logistic regression assessed correlates of dual cigar and cigarette smoking.
Results: Age, sex, race/ethnicity, education level, and poverty status of smokers varied according to cigar type. Daily cigar smoking prevalence and number of cigars smoked per day were higher for FCs (37.3%; median: 1.6 cigars/day, respectively), than all other cigar types (6.7%–25.3%, all $p < .01$; 0.1–0.4 cigars/day, all $p < .01$, respectively); daily smoking and cigars per day were similar for nonpremium cigars and cigarillos ($p = .11$; $p = .33$, respectively). Cigarette smoking was twice as common among smokers of nonpremium cigars, cigarillos, and FCs (58.0%–66.0%) than among premium cigars (29.9%). Among current cigar smokers, FC smokers (APR = 1.23, 95% confidence interval [CI] = 1.09–1.39), other tobacco product users (APR = 1.27, 95% CI = 1.15–1.41), and those

with a GED/high school diploma or less (APR = 1.20, 95% CI = 1.09–1.33) were more likely to also smoke cigarettes.

Conclusion: User characteristics, cigar smoking patterns, and dual smoking with cigarettes varied by cigar type highlighting the importance of adequately describing the cigar type studied and, where appropriate, differentiating results by cigar type.

Implications: Despite the diversity of the cigar market place, historically many research studies and tobacco surveillance systems have treated cigars as a single product type. This study describes similarities and differences in the user characteristics, tobacco use patterns, and purchasing behaviors of premium, nonpremium, cigarillo, and filtered cigar smokers. To enhance tobacco regulatory science, sufficient descriptions of the cigar type(s) studied and, where appropriate, differentiation of the particular cigar type(s) studied should be undertaken to improve the interpretation of study findings, understanding of cigar use patterns and related behaviors and future approaches to reducing cigar-attributable morbidity and mortality.

Introduction

Annual cigar consumption in the United States doubled from 6.2 billion cigars in 2000 to 12.0 billion cigars in 2016.[1] Cigar smoke contains many of the same toxic and carcinogenic constituents present in cigarette smoke.[2] Regular cigar smoking is estimated to cause approximately 9000 premature deaths annually in the United States primarily from cancers of the lung and upper aerodigestive tract, cardiovascular disease, and chronic obstructive pulmonary disease.[3] Despite the growth in cigar consumption and serious health risks associated with cigar smoking,[2–4] data systems that monitor tobacco use generally provide less detailed information on cigar smoking behaviors and product attributes as a whole and by subtypes compared with data collected for cigarettes.[5–14] Furthermore, data on purchasing behaviors, including where, how, and at what price cigars are bought, as well as beliefs about smoking particular cigar types, have not previously been systematically collected.

Federal regulations define a cigar as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco."[15] For federal tax purposes, the US Treasury Department differentiates cigars by weight as either small (≤3 pounds per 1000 cigars) or large (>3 pounds per 1000 cigars).[15] Yet, cigars come in a range of shapes and sizes, and vary in their manufacturing processes, packaging sizes, and prices; to date, no federal regulatory definitions further classify cigars to account for the diverse array of products[16] and the myriad of ways they are marketed to the public and referred to by consumers.[15–20] In a previous national telephone-based survey, cigars were distinguished into three types: premium large cigars, cigarillos, and other mass-market (ie, nonpremium) cigars, and filtered cigars (FCs), based on the size/length, components (eg, filters, tips), and cigar brand that was usually smoked.[21] In general, premium cigars, also referred to as "stogies," consist of more expensive tobacco varieties and components, such as whole tobacco leaf wrapper and binder, and may be assembled by hand. Cigarillos and other larger mass market cigars are generally machine-produced using homogenized tobacco leaf or reconstituted tobacco, and may be sold with plastic or wooden tips. FCs are generally similar to cigarettes in shape, size, and other features and are generally sold in packs or by the carton, like cigarettes.[22–24]

Preference for particular cigar types can vary according to individual user characteristics (eg, sex, age, socioeconomic status), frequency (eg, daily vs. some days) and the extent of co-use with other substances, including cigarettes and marijuana.[9,11,21,25–27] Co-use or dual use of cigars and cigarettes has been a focus of recent studies as cigarette smoking prevalence has declined and the diversity of noncigarette tobacco products has grown.[9–11,21,27–31] Among the tobacco products that have received particular attention are "little cigars and cigarillos" (or "LCCs") and their relationship to cigarette smoking. Studies suggest that the relationship between LCCs and cigarette smoking is influenced by factors such as (1) differences in local, state and federal tobacco tax rates, (2) regulations on cigarette flavoring, minimum pack sizes, and advertising restrictions, (3) marketing strategies, including price promotions by tobacco manufacturers, and (4) perceptions among young people about the risks or harms of smoking cigars generally or relative to cigarette smoking.[11,27,28,32–34] Related work has explored how LCC risk perceptions vary according to tobacco flavorings and co-use of other substances.[31,35] However, to date, information specific to each cigar type has been limited, as has data on a full range of tobacco-related behaviors.

The current study describes individual user characteristics, tobacco use patterns, purchasing behaviors, and reasons for use separately for traditional premium and nonpremium cigars, cigarillos, FCs, and cigarettes. This analysis adds to the small body of empirical evidence on the similarities and differences across cigar types and cigarettes. These comprehensive data can provide a better understanding of the cigar marketplace and inform future strategies to reduce the death and disease from cigar smoking.

Methods

Sample

The PATH Study is a nationally representative, longitudinal cohort study of 45971 adults and youth in the United States, aged 12 years and older. The National Institutes of Health, through the National Institute on Drug Abuse, is partnering with the Food and Drug Administration's Center for Tobacco Products to conduct the PATH Study under a contract with Westat. The PATH Study uses Audio Computer-Assisted Self-Interviews to collect self-report information on tobacco-use patterns and related health behaviors. The PATH Study recruitment employed a stratified address-based, area-probability sampling that oversampled adult tobacco users, adults aged 18–24 years, and African American adults. An in-person screener was used to select youths and adults from households for participation. This analysis draws from the adult interviews (n = 32320 participants aged 18 years and older) since adults were asked more detailed tobacco purchasing questions compared with youth. Among households screened for wave 1 (weighted household screener rate = 54.0%), the overall

adult interview weighted response rate was 74.0%. The weighting procedures adjusted for oversampling and nonresponse; combined with the use of a probability sample, the weighted data allow the estimates produced by the PATH Study to be representative of the noninstitutionalized, civilian US population. Further details regarding the PATH Study design, methods, and study instrument (including cigar images) are published elsewhere.[36,37] The PATH Study was approved by the Institutional Review Board at Westat, and the Office of Management and Budget approved the data collection. This analysis relies on data collected from wave 1, fielded from September 2013 to December 2014 and analyzed in 2015–2016.

Measures

To distinguish cigar types, the PATH Study questionnaire first displays images of traditional cigars with accompanying text describing the physical characteristics and listing examples of popular brands ("*Traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others.*") Then the questionnaire displays images of cigarillos and FCs with text: "*Cigarillos and filtered cigars are smaller than traditional cigars. They are usually brown. Some are the same size as cigarettes, and some come with tips or filters. Some common brands are Black & Mild, Swisher Sweets, Dutch Masters, Phillies Blunts, Prime Time, and Winchester.*" That is followed by a question about the kind of FCs or cigarillos smoked. Participants who reported smoking cigars "*with a filter (like a cigarette filter)*" were assigned as FC smokers, whereas those reporting having smoked cigars "*with a plastic or wooden tip*" or "*without a tip or filter*" were assigned as cigarillo smokers. Nearly half of all cigarillo smokers (45%) used both tipped and untipped cigarillos. Sensitivity analyses (not shown) indicated that three groups of cigarillo users: dual tipped and untipped, tipped only, and untipped only shared similar use behaviors and profiles, consequently cigarillos were analyzed as a single category.

Current Established Cigar Smokers

Participants who had ever heard of the cigar type, ever smoked the cigar type "*fairly regularly*," and now smoked the cigar type every day or some days were defined as current established cigar smokers. Those smoking more than one of the three cigar types (ie, traditional cigar, cigarillo, FC) were administered the cigar module for each cigar type smoked. For this analysis, traditional cigars were further differentiated as premium or nonpremium based on the tobacco blends, components, manufacturing process and other characteristics associated with the usual brand smoked (Supplementary Table A). Relying on usual brand smoked, approximately 10% of traditional cigar smokers could not be assigned a premium status. Among those who *were* assigned as premium smokers, 90% paid, on average, ≥$2 per cigar, and a similar percentage assigned as nonpremium smokers paid <$2 per cigar. Therefore, those with nonusable brand information who paid ≥$2 per cigar were designated as premium cigar smokers, whereas those paying <$2 were assigned as nonpremium. This analysis comprises four cigar types: traditional premium, traditional nonpremium, cigarillos, and FCs.

Current Established Cigarette Smokers

Participants who had smoked at least 100 manufactured or roll-your-own cigarettes in their lifetime and now smoked cigarettes every day or some days were defined as current established cigarette smokers.

Cigar Smoking Patterns

For this analysis, the lifetime number of cigars smoked was categorized as: 10 or fewer cigars, 11–50 cigars, and 51 or more cigars, the upper category intended to be consistent with the lifetime threshold for cigar use applied on national adult tobacco surveys.[38,39] Daily smoking was ascertained from the frequency (ie, every day, some days) the cigar type was smoked. Number of days smoked in the past 30 days was collected continuously for some day smokers; every day smokers were assigned as smoking on all 30 days. Number of cigars smoked per day for each cigar type was calculated for daily and some day smokers; among those who smoked on 0–29 of the past 30 days, this value was calculated as the number of days smoked multiplied by the number of cigars smoked on those days divided by 30 (days). Duration of smoking was calculated by subtracting age at first regular use from current age. Current use of ≥1 other noncigar, noncigarette product(s) was defined as having ever used at least one of the following tobacco products "fairly regularly" and now using that product every day or some days: e-cigarettes, pipe tobacco, hookah, snus pouches, other smokeless tobacco (ie, loose snus, moist snuff, dip, spit, chewing tobacco), or dissolvable tobacco.

Cigar Purchasing

Participants reported whether they had a regular brand, the name of the regular brand, and whether the brand was flavored. They also indicated how (in person, from the internet, by telephone or did not buy their own tobacco product) and where (convenience store/gas station, smoke shop/tobacco specialty or outlet store, or somewhere else) they purchased cigars. Participants reported their usual cigar purchase size as single stick or box/pack. Price per cigar was calculated as the usual price the participant reported paying divided by the number of cigars sold in the usual unit purchased. For cigarette smokers, corresponding smoking and purchasing measures were created and reported when applicable.

Reasons for Cigar Smoking

Participants were asked a total of 12 reasons or beliefs (in a randomized order) why people may smoke cigars and indicated whether each applied to them ("yes"/"no"). Reasons included: "*They are affordable*"; "*I like socializing while smoking them*"; and "*They come in flavors I like.*" The full set is reported in Supplementary Table B. Reasons that included comparisons to cigarettes were stratified according to the participant's cigarette smoking status.

Demographic Characteristics

Participants reported the following demographic characteristics: sex (male, female); age in years, categorized as: 18–24, 25–34, 35–54, ≥55; race and ethnicity, categorized as: white non-Hispanic (NH) ("white"), black/African American NH ("black"), other/multi-race NH, Hispanic; education status, categorized as: less than high school diploma, GED, high school diploma, some college/associate's degree, completed college or more. Based on annual household income and household size, poverty status was assigned following federal guidelines as: <100% federal poverty level (FPL), 100–<200% FPL, and ≥200% FPL.

Data Analysis

Prevalence estimates for smoking each of the four cigar types and cigarettes were produced in SAS version 9.3 (SAS Institute, Cary, NC) according to demographics, tobacco use patterns, purchasing behaviors, and reasons for use. Tests for differences among smokers of each of the four cigar types or cigarettes were conducted in SAS using

simple linear regression for categorical variables, and were conducted in Stata version 14.2 (StataCorp, College Station, TX) using quantile regression for continuous variables not normally distributed. Adjusted prevalence ratios (APRs) were obtained using a marginal predictions approach with logistic regression[40] in SAS-callable SUDAAN version 11.0.1 (RTI International, RTP, NC) to examine associations between dual cigar and cigarette smoking versus cigar-only smoking according to demographics and cigar use behaviors. All analyses were conducted using replicate weights and balanced repeated replication methods (BRR) to account for the PATH Study's complex survey design.[36,37] For the tests of differences described above, the BRR method implicitly accounts for any correlation between the estimates of groups being compared.[41] Prevalence estimates with a relative standard error of >30% or denominator with <50 observations were suppressed. Variables missing values for >5% of all eligible responses (eg, FPL) were treated as a separate analytic category; otherwise, observations with missing values were dropped from analysis.

Results

Demographic Characteristics of Cigar and Cigarette Smokers

The overall prevalence of current established adult tobacco use was 0.7% for premium cigars, 0.8% for nonpremium cigars, 1.7% for cigarillos, 0.9% for FCs, and 18.1% for cigarettes (Table 1). Males comprised the majority of adult cigar (68.6%–95.8%) and cigarette (55.3%) smokers. Younger adults (aged 18–34 years) accounted for 64.5% of cigarillo smokers and 34.0%–46.8% of smokers of the other products (ie, premium cigars, nonpremium cigars, FCs). Black adults comprised 35.7% of cigarillo and 24.2% of nonpremium cigar smokers and 5.3%–15.7% of smokers of other products. Adults with a GED/high school diploma or less accounted for most smokers of cigarettes (54.8%) and all cigars (54.0%–59.2%) except premium cigars (26.2%). Adults living below the federal poverty level comprised 34.2% of cigarette and 41.2%–47.1% of all cigar smokers, except premium cigars (14.2%).

Cigar and Cigarette Smoking Patterns

Although most established cigar smokers (62.0%–71.6%) had smoked more than 50 of that cigar type in their lifetime, cigar smoking patterns and tobacco use behaviors varied by cigar type (Table 2). Prevalence of daily smoking was higher for FCs (37.3%), compared with all other cigar types (6.7%–25.3%; all $p < .01$); daily smoking was similar for nonpremium cigars and cigarillos ($p = 0.11$). Cigars smoked per day were greater for FCs (median: 1.6 cigars/day) compared with all other cigar types (0.1–0.4 cigars/day; all $p < .01$); cigars per day were similar for nonpremium cigars and cigarillos ($p = .33$). Age at first regular use was higher for FCs (median:

Table 1. Demographic Characteristics of Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars[a] (*n* = 377)	Nonpremium cigars[a] (*n* = 489)	Cigarillos (*n* = 1186)	Filtered cigars (FCs) (*n* = 551)	Cigarettes (*n* = 11402)
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Overall adult prevalence	0.7 (0.6–0.7)	0.8 (0.7–0.8)	1.7 (1.5–1.8)	0.9 (0.8–1.0)	18.1 (17.6–18.6)
Sex					
Male	95.8 (93.5–98.0)	83.9 (80.2–87.6)	72.7 (70.1–75.4)	68.6 (64.6–72.7)	55.3 (54.2–56.4)
Female	4.2 (2.0–6.5)	16.1 (12.4–19.8)	27.3 (24.6–29.9)	31.4 (27.3–35.4)	44.7 (43.6–45.8)
Age group (years)[b]					
18–24	17.5 (12.3–22.6)	22.1 (18.3–25.9)	35.9 (32.5–39.3)	18.0 (14.2–21.7)	14.1 (13.3–14.8)
25–34	25.5 (20.0–31.0)	24.7 (20.3–29.2)	28.6 (25.2–31.9)	16.0 (12.4–19.6)	24.3 (23.4–25.1)
35–54	34.4 (29.3–39.6)	32.9 (27.7–38.2)	27.1 (23.9–30.2)	39.8 (35.3–44.3)	39.0 (38.0–40.1)
55+	22.6 (17.6–27.6)	20.2 (15.8–24.6)	8.5 (6.6–10.4)	26.3 (22.0–30.5)	22.7 (21.8–23.5)
Race/ethnicity					
White, non-Hispanic	77.2 (71.9–82.4)	58.2 (53.3–63.2)	41.7 (38.3–45.0)	66.2 (61.5–70.9)	69.8 (68.6–71.0)
Black/AA, non-Hispanic	5.3 (2.3–8.3)	24.2 (19.5–28.9)	35.7 (32.1–39.2)	15.7 (11.0–20.4)	12.9 (12.2–13.7)
Other or multi-race, non-Hispanic	6.6 (3.6–9.6)	5.9 (3.5–8.2)	6.6 (5.3–7.9)	6.6 (4.3–8.9)	6.0 (5.5–6.5)
Hispanic	10.9 (7.3–14.6)	11.7 (8.6–14.8)	16.0 (14.0–18.0)	11.5 (8.7–14.3)	11.2 (10.6–11.9)
Education					
Less than high school diploma	5.4 (3.1–7.8)	14.2 (10.7–17.8)	16.0 (13.9–18.1)	17.7 (14.5–21.0)	15.9 (15.2–16.7)
GED	4.6 (2.3–6.8)	12.2 (9.3–15.1)	11.7 (10.0–13.5)	11.7 (8.8–14.6)	10.8 (10.1–11.6)
High school diploma	16.2 (12.0–20.4)	28.4 (24.2–32.5)	26.3 (23.2–29.3)	29.8 (25.3–34.3)	28.1 (26.9–29.4)
Some college/associate degree	34.9 (29.6–40.3)	38.5 (34.0–43.0)	38.2 (35.0–41.4)	33.0 (29.2–36.9)	33.8 (32.7–35.0)
Completed college or more	38.9 (33.2–44.5)	6.7 (4.3–9.2)	7.8 (6.1–9.6)	7.8 (5.1–10.4)	11.2 (10.6–11.9)
Household poverty					
<100% FPL	14.2 (10.7–17.7)	41.2 (36.4–46.0)	47.1 (43.6–50.5)	44.9 (40.1–49.8)	34.2 (32.9–35.4)
100–<200% FPL	15.4 (11.4–19.3)	22.2 (18.6–25.9)	23.6 (20.9–26.3)	27.4 (23.1–31.8)	25.1 (24.2–26.0)
≥200% FPL	62.7 (57.3–68.0)	29.0 (24.3–33.6)	22.6 (19.1–26.0)	18.4 (15.2–21.7)	32.3 (30.9–33.6)
Missing FPL	7.8 (4.7–10.8)	7.6 (5.1–10.1)	6.8 (4.9–8.7)	9.2 (6.2–12.2)	8.5 (7.8–9.2)

CI, Wald confidence interval; AA, African-American; GED, General Education Development certificate; FPL, federal poverty level.

[a]Among traditional established cigar smokers 3% (*n* = 24) could not be assigned as either a premium or nonpremium smoker after assessing responses to usual brand (Supplementary Table A).

[b]When respondent age was missing, imputed values for age were used as described in the PATH Restricted Use File User Guide (United States Department of Health and Human Services, 2017).

Table 2. Smoking Patterns Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars	Nonpremium cigars	Cigarillos	Filtered cigars (FCs)	Cigarettes[a]
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Lifetime cigars smoked					
<1–10 cigars	4.9 (2.8–7.1)	16.8 (13.5–20.1)	7.8 (6.2–9.4)	8.1 (5.3–10.8)	NA
11–50 cigars	23.4 (18.3–28.6)	21.2 (17.4–25.1)	20.9 (18.4–23.4)	21.1 (17.0–25.1)	NA
51 or more cigars	71.6 (66.5–76.8)	62.0 (57.9–66.0)	71.3 (68.6–74.1)	70.9 (67.0–74.8)	NA
Now smoke product every day	6.7 (4.1–9.3)	25.3 (21.3–29.3)	22.0 (19.7–24.2)	37.3 (31.9–42.7)	79.5 (78.5–80.6)
Days smoked in past 30 days[b] (median, IQR)	1.7 (0.0–4.8)	9.2 (1.5–28.5)	7.5 (1.3–29.1)	14.0 (0.8–28.8)	29.4 (29.1–29.7)
Number of cigars or cigarettes/day[c] (median, IQR)	0.1 (0.0–0.2)	0.4 (0.1–2.0)	0.3 (0.1–2.0)	1.6 (0.1–9.5)	10.1 (5.0–19.6)
Age (years) at first regular use[d] (median, IQR)	24.5 (18.8–32.6)	19.5 (16.6–29.6)	18.0 (15.9–23.3)	26.8 (17.8–44.3)	16.6 (14.7–18.7)
Duration (years) since first regular[d] use (median, IQR)	8.7 (3.4–16.8)	10.9 (4.3–18.0)	7.3 (3.3–13.9)	5.4 (1.7–14.4)	21.8 (10.8–35.3)
Currently use ≥1 other cigar type(s)[e,f]	16.8 (12.4–21.3)	64.0 (58.7–69.3)	37.7 (34.1–41.2)	41.6 (36.3–46.8)	9.0 (8.4–9.7)
Currently use ≥1 noncigar, noncigarette product(s)[g]	33.7 (29.5–38.0)	31.4 (26.7–36.1)	28.8 (26.0–31.6)	27.1 (23.1–31.1)	15.8 (15.0–16.6)
Cigarette smoking status[h]					
Current established smoker	29.9 (25.5–34.3)	59.5 (54.6–64.4)	58.0 (54.4–61.6)	66.0 (61.3–70.7)	NA
Former established smoker	28.3 (23.0–33.6)	15.6 (11.9–19.3)	10.6 (8.4–12.8)	10.6 (7.5–13.8)	NA
Never smoker	41.8 (36.9–46.7)	24.9 (21.0–28.9)	31.4 (28.2–34.6)	23.4 (18.9–27.8)	NA

CI, Wald confidence interval; IQR, interquartile range (25th and 75th percentiles); NA, not applicable.

[a]When respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes ($n = 554$), for certain topics they were asked separate questions about each product. For dual manufactured cigarette and RYO smokers, the responses to manufactured cigarette products are provided; otherwise, responses reflect the single cigarette type the respondent reported smoking.

[b]Number of days using the product in past 30 days was asked of those who now smoke cigars some days; every day smokers assumed to smoke on all 30 days.

[c]Respondents reporting smoking less than one cigar per day on the days smoked were assigned as smoking 0.5 cigars per day.

[d]Those reporting age at first regular use <6 years were assigned a value of 6 years.

[e]For current cigarette smokers, "currently use ≥1 other cigar products" refers to current smoking of one or more cigar products.

[f]If respondent was missing status for one cigar product and did not smoke the other cigar product, then treated as not smoking other cigar types.

[g]Current use of ≥1 noncigar, noncigarette product(s) defined as having ever used one or more of the following tobacco products "fairly regularly" and now using that product every or some days: e-cigarettes, pipe tobacco, hookah, smokeless tobacco, snus, or dissolvable tobacco. If respondent reported not using any other tobacco product, or some combination of not using and missing tobacco product use status, then treated as not using any noncigar, noncigarette products.

[h]Former established cigarette smokers had to have smoked at least 100 cigarettes in their lifetime and now smoke cigarettes not at all; never cigarette smokers had to smoke less than 100 cigarettes in their lifetime.

26.8 years) and premium cigars (24.5 years) compared with nonpremium cigars, cigarillos and cigarettes (16.6–19.5 years; all $p < .05$). Currently smoking one or more of the other cigar products ranged from 64.0% for nonpremium cigars to 16.8% for premium cigars. Current cigarette smoking was twice as common for those smoking nonpremium cigars, cigarillos, and FCs (58.0%–66.0%) than premium cigars (29.9%), and cigarette smoking status among those smoking FCs differed from that of cigarillos and premium cigars ($p < .01$). The use of noncigar/noncigarette tobacco products was lower among those smoking FCs (27.1%) than among those smoking premium cigars (33.7%; $p = .03$), and was similar to those smoking nonpremium cigars (31.4%; $p = .16$) and cigarillos (28.8%; $p = .46$).

Tobacco Product Characteristics and Purchasing Behaviors

Having a regular tobacco brand was reported by at least three-quarters (77.1%–93.1%) of smokers of nonpremium cigars, cigarillos, FCs, and cigarettes versus half (49.7%) of smokers of premium cigars (Table 3). Swisher Sweets was among the leading brands of nonpremium cigars, cigarillos, and FCs (21.7%–23.6%). Dutch Masters, Black & Mild, and White Owl brands were together reported by 59.3% of cigarillo and 32.8% of nonpremium cigar smokers, while Cheyenne, Phillies, and Prime Time were together reported by nearly 30% of FC smokers. Reporting use of a flavored usual brand occurred less frequently for premium cigars (11.9%) compared with all other cigar types (53.0%–61.0%, all $p < .01$). Nearly all nonpremium cigars, cigarillos, FCs, and cigarettes were purchased in person (95.5%–97.2%) and most were bought in convenience stores/gas stations (75.4%–86.8%). In contrast, for premium cigars, nearly one-quarter of smokers did not buy in person; smoke shops/specialty stores (46.8%) and cigar bars (29.9%) were the primary purchase locations. The median price paid per stick was lower for FCs ($0.12) than cigarettes ($0.27), nonpremium cigars or cigarillos ($1.00), or premium cigars ($7.49) (all $p < .01$).

Factors Associated With Dual Cigar and Cigarette Smoking Versus Cigar-Only Smoking

Among current cigar smokers, those smoking FCs were more likely to be dual cigarette smokers (APR = 1.23, 95% CI = 1.09–1.39), while those smoking premium cigars were less likely to also smoke

Table 3. Tobacco Product Characteristics and Purchasing Behaviors Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars	Nonpremium cigars	Cigarillos	Filtered cigars (FCs)	Cigarettes[a]
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Has a regular brand	49.7 (44.4–54.9)	77.1 (73.8–80.5)	83.0 (80.8–85.3)	82.9 (79.4–86.4)	93.1 (92.5–93.6)
Top 5 brands smoked[b]	Cohiba 16.9 (12.8–20.9)	Swisher Sweets 21.7 (17.0–26.3)	Black & Mild 42.8 (39.4–46.2)	Swisher Sweets 22.5 (17.7–27.4)	Marlboro 38.3 (36.8–39.8)
	Macanudo 15.2 (11.4–19.0)	Dutch Masters 16.7 (13.0–20.5)	Swisher Sweets 23.6 (20.9–26.3)	Cheyenne 13.4 (10.3–16.5)	Newport 14.6 (13.4–15.8)
	Arturo Fuente 13.5 (9.6–17.5)	Backwoods 11.3 (8.1–14.5)	White Owl 10.5 (8.5–12.5)	Phillies 7.9 (5.3–10.4)	Camel 10.1 (9.3–10.9)
	Acid 6.9 (3.6–10.1)	Black & Mild 9.7 (6.7–12.6)	Dutch Masters 6.0 (4.3–7.6)	Prime Time 7.2 (4.1–10.4)	Pall Mall 6.5 (5.8–7.1)
	Montecristo 6.5 (3.1–9.9)	White Owl 6.4 (4.0–8.8)	Zig Zag 2.2 (1.3–3.1)	Djarum 6.8 (4.1–9.4)	Kool 2.6 (2.0–3.3)
Regular brand flavored or mentholated[b,c,d]	11.9 (8.0–15.8)	53.0 (47.7–58.3)	61.0 (57.5–64.5)	60.4 (56.3–64.4)	37.1 (35.8–38.4)
Usually buy in person	77.6 (72.8–82.4)	96.7 (94.8–98.6)	96.7 (95.7–97.8)	95.5 (93.4–97.7)	97.2 (96.9–97.6)
Where buy tobacco product[e]					
Cigar bar	29.9 (24.1–35.6)	*	^	*	NA
Convenience store/gas station	18.2 (13.6–22.8)	78.5 (74.1–83.0)	85.1 (82.5–87.7)	75.4 (70.6–80.2)	86.9 (85.2–88.5)
Smoke shop/tobacco specialty or outlet store	46.8 (40.5–53.2)	18.4 (14.5–22.4)	12.2 (9.8–14.7)	22.0 (17.5–26.5)	10.9 (9.3–12.5)
Somewhere else	5.1 (2.2–8.0)	*	*	*	2.2 (1.5–2.9)
Usual purchase size[f]					
Single	79.1 (73.6–84.6)	44.5 (39.5–49.5)	49.4 (46.1–52.7)	13.8 (10.6–17.0)	1.8 (1.5–2.1)
Box or pack	20.9 (15.4–26.4)	55.5 (50.5–60.5)	50.6 (47.3–53.9)	86.2 (83.0–89.4)	82.0 (80.6–83.3)
Carton	NA	NA	NA	NA	16.2 (14.8–17.6)
Price per stick[f,g] (median, IQR)	$7.49 (4.53–9.93)	$1.00 (0.60–1.40)	$1.00 (0.60–1.10)	$0.12 (0.08–0.26)	$0.27 (0.23–0.32)

CI, Wald confidence interval; IQR, interquartile range (25th and 75th percentiles); NA, not applicable.

[a]When respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes ($n = 554$), for certain topics they were asked separate questions about each product. For dual manufactured cigarette and RYO smokers, the responses to manufactured cigarette products are provided; otherwise, responses reflect the single cigarette type the respondent reported smoking.

[b]Among those with a regular brand or if no regular brand, then refers to last brand purchased.

[c]Cigar and RYO smokers were asked whether their regular brand was flavored to taste like menthol, mint, clove, spice, candy, fruit, chocolate, alcohol or other sweets.

[d]Manufactured cigarette and RYO smokers were asked whether their regular brand was mentholated.

[e]Only asked of those who usually buy in person. Where buy tobacco product refers where purchasing most of the time. "Convenience store/gas station" category also includes supermarket, grocery store, warehouse, liquor store; "somewhere else" category also includes duty free shop, military commissary, bar/pub, restaurant, casino, friend, relative, swap meet/flea market, store on an Indian reservation.

[f]For cigar smokers, restricted to usually buy in person; for cigarettes, asked of manufactured cigarette smokers, irrespective of buying in person or not.

[g]Among FC smokers, price per stick is restricted to those who reported purchasing either 20 or 12 count packs (63% of all FC smokers).

*Estimate has been suppressed because it is statistically unreliable. It is based on a (denominator) sample size of less than 50, or the relative standard error of the estimate (or its complement) is larger than 30 percent.

^The estimate's 95% CI is (0.7–2.3); the estimate is reliable however it is not reported to avoid deducing the value of the suppressed estimate in this column.

cigarettes (APR = 0.52, 95% CI = 0.40–0.67) (Table 4). Cigar smokers who currently used additional tobacco products (eg, e-cigarettes, hookah, smokeless tobacco) were more likely to also smoke cigarettes (APR = 1.27, 95% CI = 1.15–1.41). Compared to whites, black cigar smokers (APR = 0.82, 95% CI = 0.72–0.94) were less likely to also smoke cigarettes. Cigar smokers with a GED/high school diploma or less were more likely (APR = 1.20, 95% CI = 1.09–1.33) than those with at least some college to also smoke cigarettes. Those who reported smoking any cigar type on a daily basis were less likely to smoke cigarettes (APR = 0.88, 95% CI = 0.78–0.99) than those who did not smoke any cigar type on a daily basis.

Reasons for Using Cigar Products

Socializing when smoking cigars (49.9%–76.6%) and availability of cigars in flavors (48.6%–71.9%) were reasons endorsed by half or more of smokers of all cigar types, while other reasons for use varied by cigar type and cigarette smoking status (Supplementary Table B). Affordability was endorsed by most of those smoking FCs (80.2%), cigarillos (71.7%), and nonpremium cigars (66.4%), but not for those smoking premium cigars (22.7%). More than half of FC smokers overall (52.4%), including 56.2% who also currently smoked cigarettes and 61.0% who formerly smoked cigarettes, indicated FCs were like smoking a regular cigarette, compared with only 6.3%–26.8% of other cigar types.

Table 4. Percent of Dual Cigar and Cigarette Smokers Among Adult Current Established Cigar Smokers and Adjusted Prevalence Ratios by Demographic and Cigar Smoking Characteristics, PATH Study Wave 1, 2013–2014

	Prevalence (95% CI)	Adjusted PR[a] (95% CI)
Smoke premium cigars		
Yes	29.9 (25.5–34.3)	0.52 (0.40–0.67)
No	60.3 (57.2–63.4)	Ref
Smoke nonpremium cigars		
Yes	59.5 (54.6–64.4)	0.97 (0.86–1.09)
No	52.1 (49.0–55.2)	Ref
Smoke cigarillos		
Yes	57.9 (54.4–61.5)	1.09 (0.95–1.25)
No	48.7 (44.9–52.6)	Ref
Smoke filtered cigars (FCs)		
Yes	66.0 (61.3–70.7)	1.23 (1.09–1.39)
No	48.7 (45.9–51.4)	Ref
Use other tobacco products[b]		
Yes	62.1 (57.7–66.4)	1.27 (1.15–1.41)
No	50.4 (47.1–53.7)	Ref
Sex		
Male	51.7 (48.7–54.7)	Ref
Female	59.9 (54.7–65.1)	1.01 (0.91–1.13)
Age group (years)		
18–34	55.1 (51.9–58.4)	0.98 (0.89–1.07)
35+	52.1 (47.8–56.3)	Ref
Race/ethnicity		
White, non-Hispanic	55.2 (51.4–59.1)	Ref
Black/AA, non-Hispanic	49.5 (44.5–54.6)	0.82 (0.72–0.94)
Other/multi-race, or Hispanic	53.0 (47.1–58.9)	0.90 (0.80–1.02)
Education		
GED, HS diploma or less	61.7 (58.5–64.9)	1.20 (1.09–1.33)
Some college/associate degree or more	45.9 (42.2–49.6)	Ref
Daily cigar smoking[c]		
Yes	53.8 (48.4–59.2)	0.88 (0.78–0.99)
No	53.5 (50.5–56.6)	Ref

CI, logit-transformed confidence interval; PR, prevalence ratio; AA, African-American; HS, high school; GED, General Education Development certificate.
[a]There were $n = 2045$ current established cigar smokers with information on current cigarette smoking status. The regression analysis included $n = 1895$ participants ($n = 834$ cigar only; $n = 1061$ dual cigar + cigarette) after observations missing information for ≥1 covariate were excluded.
[b]Use of other tobacco products defined as having ever used one or more of the following tobacco products "fairly regularly" and now using that product every day or some days: e-cigarettes, pipe tobacco, hookah, smokeless tobacco, snus, or dissolvable tobacco.
[c]Daily cigar refers to smoking at least one cigar type on a daily basis.

Discussion

While historically many research studies and tobacco surveillance systems have treated cigars as a single product type, the PATH Study fills an important gap by providing detailed information on individual user characteristics, tobacco use patterns, purchasing behaviors, and reasons for use separately for traditional cigars, cigarillos, and FCs. Examination by cigar type revealed similarities and differences in demographic and behavioral outcomes. Compared with smokers of traditional-sized premium cigars, those smoking nonpremium cigars tended to be more like cigarillo smokers in demographics, smoking frequency, brand preferences, and purchasing behaviors (eg, price), suggesting nonpremium cigars and cigarillos may be studied jointly in future work. We also found FCs tended to differ from other cigar types including more frequent daily use, greater numbers of cigars smoked per day and older age at first regular use, which, in conjunction with endorsed reasons for use and other measures, suggests that FCs may be smoked in place of cigarettes. Finally, those smoking premium cigars tended to differ from those smoking nonpremium cigars, cigarillos, and FCs including having users with higher socioeconomic status, lower smoking frequency, different purchasing behaviors (eg, where and for how much cigars were bought) and reasons for use.

Several recent studies have examined the characteristics, behaviors, and risk perceptions of LCC smokers.[9–11,26–30,35] Tobacco manufacturers and researchers apply the term "little cigar" interchangeably with FCs, making it difficult to distinguish whether LCC smoking includes use of cigarette-like cigars with filters, larger cigarillo-like unfiltered cigars, or both. Our findings that smokers of FCs tended to differ from cigarillo smokers by frequency and number of cigars per day, age at first use, and the likelihood of cigarette smoking, suggests that future studies should clearly describe the cigar types smoked and differentiate the cigar types analyzed. Despite these notable differences, our results align with prior studies that compared smokers of *any* mass-marketed cigar (eg, users of Black and Milds, Swisher Sweets, Phillies Blunts, Captain Black brands) with traditional large cigar smokers.[9,11,42] Specifically, those who reported smoking nonpremium cigars, cigarillos or FCs tended to be younger, non-Hispanic black, have low educational attainment, live below 200% of the federal poverty line, and smoke cigars on a daily basis as compared with those who smoked premium cigars.

This study is among the first to examine correlates of dual cigar and cigarette smoking *among current cigar smokers*. We found that dual users, relative to cigar-only smokers, were more likely to smoke FCs, use other noncigar/noncigarette tobacco products, and have lower educational attainment. One previous study that assessed factors associated with poly-tobacco use (ie, use of cigarettes, chewing tobacco, or snuff) among cigar smokers also found that poly-use was associated with lower levels of education.[21]

Our findings align and advance prior qualitative work that indicated FCs may be marketed to and smoked by consumers as inexpensive substitutes for cigarettes.[12,13] In adjusted analyses accounting for demographic factors and other tobacco use, only those who reported smoking FCs were significantly more likely to report dual use with cigarettes. Most FC smokers who currently or formerly smoked cigarettes agreed that smoking FCs felt like smoking a regular cigarette. Of note, the median age at first regular use of FCs was nearly a decade older than first regular use of cigarettes, indicating that most FC smokers take up FCs in adulthood rather than during adolescence. Those findings, in conjunction with the median price paid per FC being approximately half that of a cigarette, and high endorsement of affordability as a reason for smoking FCs, add further evidence that FCs may be smoked in place of cigarettes.

This analysis differentiated traditional cigar smokers as either premium or nonpremium based on usual brand and price. Since regulatory definitions of premium cigars do not exist, information about the brand's tobacco blends, components (eg, long filler, whole leaf wrapper), and manufacturing process (eg, handmade), obtained through online searches, was used to distinguish premium from nonpremium brands. Where brand information was unavailable, usual price paid per stick of ≥$2 was applied to identify premium brands, allowing us to classify more smokers than was possible in previous studies.[21] Although the results illustrate clear distinctions between premium and nonpremium smoker characteristics, use patterns and purchasing behaviors, some traditional cigar smokers may have been misclassified using this approach.

Because detailed product use and purchasing questions were asked of those who "*ever fairly regularly*" smoked cigars, this analysis characterizes a population of more established cigar smokers. The adult prevalence of *experimental* cigar smoking (defined as never fairly regularly smoking cigars and now smoking every or some days) was considerably higher than established cigar smoking. Supplementary Table C provides demographic characteristics of *all* adults now smoking cigars every day or some days, irrespective of ever fairly regularly smoking cigars. This broader definition may be more consistent with the population of current cigar smokers that are captured and reported in national tobacco surveys.[1,3,10]

This study estimated the median number of cigars smoked per day according to each cigar type. It should be noted that the size (ie, weight) of each cigar type varied, which precluded us from making comparisons that standardized the amount smoked for each cigar type. Our understanding of cigar toxicant exposures in general and whether exposures vary according to cigar type will be enhanced through future analyses of PATH Study biomarkers data. Finally, this study did not assess blunt use, whereby part or all of the cigar tobacco filler is replaced with marijuana before it is smoked. Since blunt use can be common among adolescent and adult cigarillo smokers, and in particular, untipped cigarillos users,[14,15,22–24] future analyses of cigar smoking behaviors may explore the influence of blunt use among cigarillo subtypes and assess levels of toxicant exposures among blunt and nonblunt users.

While cigars are a combustible tobacco product and carry many of the same health risks as cigarettes, historically, tobacco control policies focused on cigarettes.[14] Our results may be useful to inform tobacco control efforts related to cigar smoking. Most importantly, our data point to adequately describing the cigar type(s) studied, rather than using non-specific terms like "little cigars" or "LCCs," and to differentiating results by cigar type, where appropriate, to enhance tobacco research and surveillance. Our findings that nonpremium cigars, cigarillos, and FCs are more likely to be flavored compared with cigarettes, that FCs had lower median price per stick ($0.12) compared with cigarettes ($0.27), and that usual pack size for cigar smokers is more likely to be a "single" stick compared with cigarettes all highlight product features of cigars that tobacco control and regulatory science research could address. In fact, focus is beginning to shift to noncigarette tobacco products, including cigars.[16–19] For example, New York City, Chicago, and Providence, RI have implemented policies restricting the sale of flavored cigars, while Boston has imposed minimum pack sizes for cigars. Additional tobacco control efforts at local, state, and national levels can reduce the morbidity and mortality associated with use of all cigar types.

Supplementary Material

Supplementary data is available at *Nicotine & Tobacco Research* online.

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Declaration of Interests

Authors do not have any competing interested to report. Additionally, authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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EXHIBIT 3

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ECONOMIC CONSULTING

Faten Sabry, PhD
Managing Director

National Economic Research Associates, Inc.
1166 Avenue of the Americas
New York, New York 10036
+1 212 345 3000 Fax +1 212 345 4650
Direct dial: +1 212 345 3285
faten.sabry@nera.com
www.nera.com

July 16, 2018

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

RE: Docket No. FDA-2017-N-6189 Regarding the Regulation of Nicotine Levels

Dear Sir/Madam:

I appreciate the opportunity to provide comments regarding the regulatory actions that the Food and Drug Administration is considering regarding the regulation of nicotine levels.

I am a managing director in the mass torts and securities practices at NERA Economic Consulting in New York. I am an economist by training and have over 25 years of experience in economic consulting on issues related to product liability, mass torts, consumer behavior, complex damages disputes and securities. I have consulted on numerous matters involving consumer behavior, quantified tort liabilities and conducted economic impact studies. I have testified before the U.S. Department of Labor's Hearings on an economic and statistical analysis of the methodology used to quantify the expected benefits of the proposed rule regarding silica.[1] I have also recently submitted comments regarding the CFPB's request for changing the Bureau's public reporting practices of consumer complaint information and have conducted studies on the economic impact of smoking bans.[2] I received my Ph.D. from Stanford University and have been designated by the American Statistical Association as an Accredited Professional Statistician. I have published on issues related to tort reforms, propensity to seek legal actions, mutual funds fees, and the impact of the credit crisis, among other issues, in the *Journal of Structured Finance*, *Journal of Investment Compliance*, *Journal of Alternative Investments*, *Business Economics*, *International Trade Journal*, and others.

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

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

I have been asked by the Cigar Rights of America, the Cigar Association of America, and the International Premium Cigar and Pipe Retailers Association to provide an empirical analysis of consumers' behavior regarding the dual use of premium cigars and cigarettes. I relied on Corey et al. (2017) for the definition of premium cigars and also relied on the same PATH database, Wave 1, to examine the consumption patterns of premium cigars.[3] I will be providing additional analysis in response to the comment docket regarding the regulation of premium cigars on July 25, 2018.

Using the same PATH database and definitions used in the Corey study, I further analyzed the consumption patterns of current premium cigar smokers.[4] First, I compared the frequency and intensity of premium cigar use among current premium cigar smokers depending on whether they are also current cigarette smokers. Exhibit 1 shows the frequency and intensity for premium cigar smokers who are also current cigarette smokers and those who are not. According to the PATH data, respondents who reported smoking less than one cigar per day were assigned as smoking 0.5 cigars per day. Among current premium cigar smokers, those who are also current cigarette smokers smoke premium cigars 1.1 days per month as compared to 1.9 days per month for those who are not current cigarette smokers. Premium cigars consumed per day, among these two groups, were 0.6 cigars per day among current cigarette smokers and 0.7 cigars per day for those who are not current cigarette smokers.

[3] Corey, C.G., E. Holder-Hayes, A.B. Nguyen, et al. "U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014", *Nicotine & Tobacco Research*, September 15, 2017, available at: https://academic.oup.com/ntr/article/4159211/U-S-adult-cigar-smoking-patterns-purchasing.

[4] I was able to replicate Corey et al. (2017) with respect to the overall premium cigar prevalence rate and dual use of cigarettes and premium cigars finding.

Exhibit 1. *Frequency and Intensity of Premium Cigar Use Among Current Premium Cigar Smokers*

	Current Cigarette Smokers?	
	Yes	No
	(1)	(2)
Days smoked premium cigars in past 30 days[1]		
Median	1.1	1.9
Interquartile range	(0.0-4.3)	(0.2-5.0)
Number of premium cigars per day[2]		
Median	0.6	0.7
Interquartile range	(0.0-0.9)	(0.1-0.9)
Number of observations	125	252

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

[1] Number of days smoked in the past 30 days is available for someday smokers. Everyday smokers are assumed to smoke on all 30 days.

[2] Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

Second, I calculated additional summary statistics on cigars and cigarettes consumption. Exhibit 2 presents frequency and intensity of cigarette smoking among current cigar smokers. The exhibit shows that the typical current premium cigar smoker did not smoke cigarettes on any day in the past 30 days.[5] The median number of cigarette smoking days and the median number of cigarettes per day are both zero. By contrast, the typical current non-premium cigar smoker smoked cigarettes on 29.0 of the past 30-day period, and typically smoked 5.2 cigarettes a day. The typical current cigarillo smoker smoked cigarettes on 19.9 days of the past 30-day period and smoked 4.2 cigarettes a day. The typical current filtered cigar smoker smoked cigarettes on 29.2 days of the past 30-day period and smoked 9.2 cigarettes a day.

[5] The typical current premium cigar smoker is represented by the median observation. The median observation is the middle point value separating the higher half of the observations from the lower half.

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Exhibit 2. *Frequency and Intensity of Cigarette Use Among Current Cigar Smokers*

	Premium Cigars (1)	Non-Premium Cigars (2)	Cigarillos (3)	Filtered Cigars (4)
Days smoked cigarettes in past 30 days[1]				
Median	0.0	29.0	19.9	29.2
Interquartile range	(0.0-28.1)	(0.0-29.5)	(0.0-29.5)	(1.4-29.6)
Number of cigarettes per day				
Median	0.0	5.2	4.2	9.2
Interquartile range	(0.0-4.5)	(0.0-18.5)	(0.0-14.7)	(0.0-18.9)
Number of observations	377	489	1,186	551

Notes and Sources:

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

[1] Everyday smokers are assumed to smoke on all 30 days. Respondents who never smoked are assumed to not smoke any days.

Yours Sincerely,

Faten Sabry

Faten Sabry
Managing Director

Rights of America with the FDA on July 25, 2018,

(https://www.regulations.gov/document?D=FDA-2017-N-6107-8796)
This comment addresses significant issues pertaining to the public health questions surrounding premium handmade cigars, including, inhalation/addiction, youth access, demographics, patterns of use, and related analysis that clearly note the need for regulatory reform as it pertains to premium handmade cigars.

Coalition of American Cigar Rollers
113 Fitzpatrick Street
Key West, Florida 33040

April 4, 2019

The Honorable Marco Rubio, Member
U.S. Senate
284 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Rubio:

The Coalition of American Cigar Rollers would like to thank you for having the hearing this week on the issue of federal regulation of premium cigars, and the impact these regulations will have on small businesses across the nation.

Our Coalition of American Cigar Rollers was founded based upon a story which was provided by Cigar Aficionado magazine that profiled the remaining businesses within the United States that roll cigars on premise, for local customers, tourists, and connoisseurs across the nation, and indeed around the world.

We are each "small batch" manufacturers that work with tobacco brought in from throughout Latin America, to produce some truly great cigars. We range from one to two rollers, to a dozen or so, many of which are direct family, making our businesses truly the American dream.

The Coalition of American Cigar Rollers now has 37 members in seventeen states, so while Florida is certainly known for its historic link to the cigar industry, our members span from the Bronx in New York City, to New Orleans, and Tulsa, Oklahoma and San Diego, California. The story listing these remaining businesses in America is attached for your review.

We simply want to convey one message: The federal government shouldn't be working to put us out of business. We are artisan craftsmen, and women, using the skills acquired through years of training and dedication, working with the all natural leaves, brought from the ground, to our shops. It's that simple. The idea that any of our businesses would be subject to having the federal government approve our blends, which could change

daily, or demand testing that none of us can afford, or destroy our packaging with unwarranted warning labels, simply should not be allowed.

We hope that your S. 9 legislation is successful in protecting our businesses, and we appreciate the introduction of H.R. 1854. This is a time for our members of Congress to work together, so that we can save jobs, preserve an art form, and prevent these regulations from ruining what it has taken generations to build.

Thank you for the opportunity to submit this statement, and please come and visit some of our shops. You'll see the dedication put into creating each cigar.

Sincerely,

Danny Difabio

Danny Difabio, National Co-Chairman
Coalition of American Cigar Rollers

50 Factories In The U.S. That Still Make Cigars

JANUARY 31, 2019 | By Gregory Mottola (/author/gregory-mottola)

A roller inside the J.C. Newman cigar factory, located in Tampa's historic Ybor City.

In 1895—when steel magnates, financiers and railroad tycoons ruled America's Gilded Age—there were around 42,000 cigar factories in the United States, with 300 in Cleveland alone. Even far-flung cities like Davenport, Iowa had a thriving cigar industry. At the time, there were so many people rolling cigars in this country that cigarmakers had their own union.

Today, it's quite rare to see a cigar factory in the U.S. And if you live in a flyover state, you probably won't find any at all. Regardless of this sad fact, we managed to find 50.

After some research, we put together a list of 50 places in the U.S. that are still sourcing tobacco and rolling their own smokes by hand, day in and day out. Some are very small, modest operations with only one or two rollers making a house brand for locals. Others are famous, places like J.C. Newman (https://www.cigaraficionado.com/articles/a-walk-through-the-historic-j-c-newman-factory), El Rey de Los Habanos (https://www.cigaraficionado.com/articles/the-next-big-thing-in-cigars-pepin-6220), Aganorsa Leaf and El Titan de Bronze, responsible for producing nationally distributed brands. A number of the locations on this list even produce handmade cigars that are highly rated by this magazine.

As you might expect, the largest concentration of cigar factories today is in Florida, namely Tampa and Miami—areas where Cuban cigar rollers have been expatriating since Castro's Revolution.

While 50 U.S. cigar factories is a far cry from 42,000, small operations like these still play a valuable part in keeping cigar culture alive. Should you find yourself in the vicinity of one of these factories, we encourage you to stop in, try a smoke and enjoy a piece of modern-day Americana.

Arizona

Willy Cigars (http://willycigars.com/)

California

Cuban Cigar Factory (http://www.cubancigarfactory.net/) (one roller), *San Diego*

Gran Havana Cigar Factory (https://granhavana.com/) (two rollers), *San Diego*

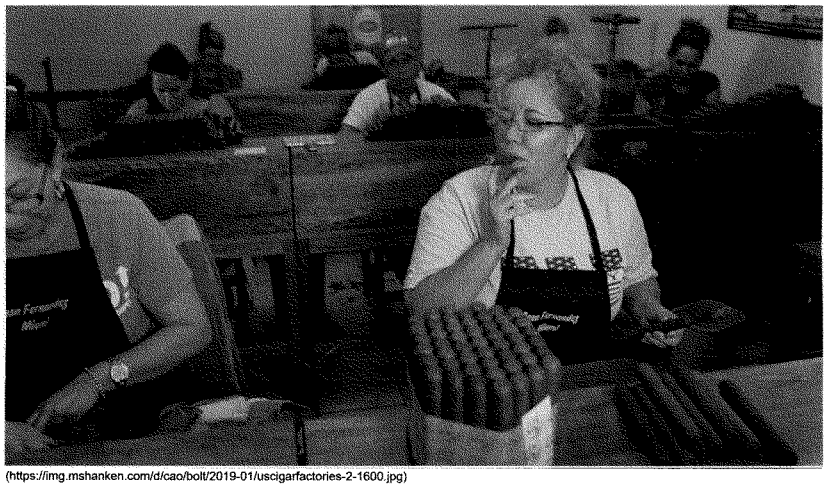
Colorado

Casa De Palma Cigar Co. (http://palmacigars.com/)

Connecticut

Cigar Factory Outlet (http://www.discountcigars.org/catalog/) (one roller, two days a week), *South Norwalk*

Connecticut Cigar Co. (http://www.ctcigarco.com/) (one roller), *Stamford*



(https://img.mshanken.com/d/cao/bolt/2019-01/uscigarfactories-2-1600.jpg)

Making cigars often means you get to smoke while you work. Inside the Aganorsa Leaf Miami cigar factory (formerly Tabacalera Tropical), a roller takes a puff of one of her handmade smokes. (Photo/Jeffery Salter)

Florida

Moore & Bode (https://www.facebook.com/MooreBodeCigars/), *Coral Gables*

Cigar Factory Social Club (https://www.cigarfactorysocialclub.com/) (one roller), *Destin*

Don Pablo Cigars (https://donpablocigars.co/), *Fort Myers*

Cuban Leaf Cigar Factory (http://www.cigars-tobacco-shopping.com/), *Key West*

The Original Key West Cigar Factory (https://kwcigarfactory.com/), *Key West*

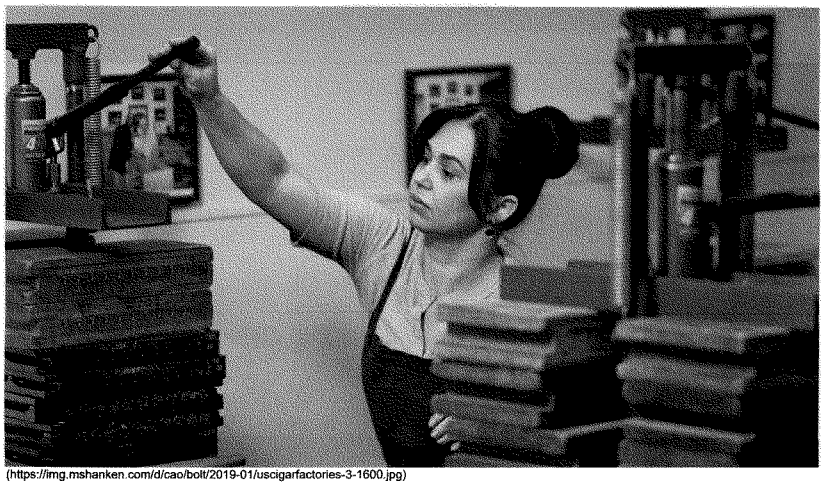
Rodriguez Cigar Factory (http://rodriguezcigarskeywest.com/), *Key West*

Aganorsa Leaf Miami (https://www.aganorsaleaf.com/) (formerly Tabacalera Tropical), *Miami*

Cuban Crafters (https://www.cubancrafters.com/miami-florida-cigar-store-and-factory/), *Miami*

Cuba Tobacco Cigar Co. (http://Cubatobaccocigarco.com), *Miami*

El Rey de Los Habanos (http://myfathercigars.com/), *Miami*



(https://img.mshanken.com/d/cao/bolt/2019-01/uscigarfactories-3-1600.jpg)

El Titan de Bronze is a boutique cigar factory and shop located in Miami's Little Havana neighborhood.(Photo/Jeffery Salter)

El Titan de Bronze (https://titandebronze.com/), *Miami*

Guantanamera Cigars (http://guantanameracigars.com/), *Miami*

Havana Classic Cigar (http://Havanaclassic.com), *Miami*

Little Havana Cigar Factory (http://www.littlehavanacigarstore.com), *Miami*

Cigar Factory Social Club (https://www.cigarfactorysocialclub.com/) (one roller), *Pensacola*

J.C. Newman (http://www.jcnewman.com/), *Tampa*

JDV Hand Rolled Cigars (http://tampa-cigar.com/), *Tampa*

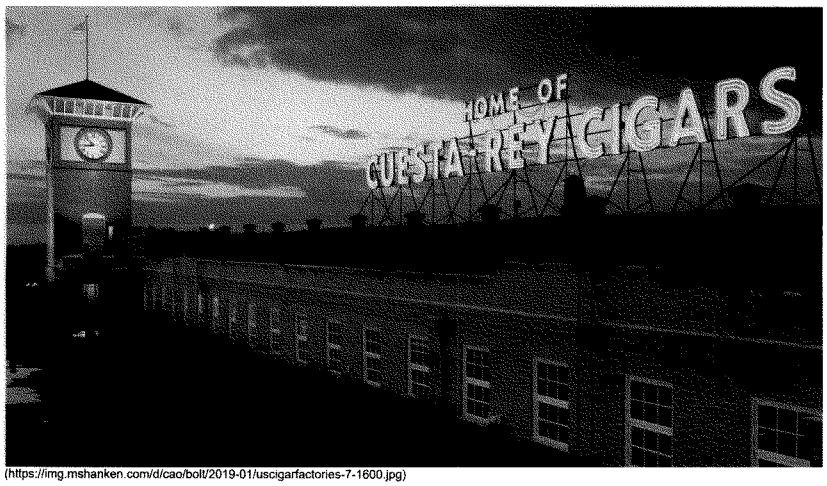
La Faraona (https://www.lafaraonacigars.com/), *Tampa*

Long Ash Cigars (https://thelongashcigars.com/), *Tampa*

Nicahabana Cigars (https://www.nicahabanacigar.com/), *Tampa*

Tabanero Cigars (https://tabanerocigars.com/), *Tampa*

Ybor Cigar Plus (https://www.yborcigarsplus.com/), *Tampa*



(https://img.mshanken.com/d/cao/bolt/2019-01/uscigarfactories-7-1600.jpg)

Most of the cigars made in Tampa's J.C. Newman cigar factory are made on antique cigar machines, but some are rolled by hand.

Kentucky

Kentucky Gentleman Cigar Co. (https://www.kentuckygentlemencigars.com/)

Illinois

Indio Cigar Factory (https://indiocigars.com/) (one roller)

Lousiana

Cigar Factory New Orleans (https://www.cigarfactoryneworleans.com/)

Massachusetts

Boston Cigar Factory (https://www.bostoncigarfactory.com/) (no retail space, but sell their own brands online and do events)

Nevada

En Fuego Cigars (http://enfuegolasvegas.com/) (one roller), *Las Vegas*

Ruiz Cigars (https://www.ruizcigars.com/), *Sparks*

New Jersey

Alvarez Cigars (http://alvarezcigars.com/), *Perth Amboy*

Hoboken Cigars (http://hobokenpremiumcigars.com/) (one roller), *Hoboken*

Jimenez Tobacco (https://www.jimeneztobacco.com/), *Newark*

Rodriguez Puros Cigars (https://www.facebook.com/pages/Rodriguez-Puros-Cigars/145869712101994), *Jersey City*

New York

D.P. Cigars (https://www.facebook.com/pages/DP-Cigars/140926185950249), *New York City (Manhattan)*

La Casa Grande (http://www.lcgcigars.com/), *New York City (Bronx)*

Martinez Cigars (http://www.martinezcigars.com/?age-verified=4bd0cedecc), *New York City (Manhattan)*

Rosario Cigars LLC (https://www.rosariocigarsllc.com/), *New York City (Bronx)*

Santiago Cigar Factory (http://santiagocigarfactory.com/), *Rochester*

North Carolina

Flor de America Cigar Factory (https://www.facigars.com/)

(https://img.mshanken.com/d/cao/bolt/2019-01/uscigarfactories-6-1600.jpg)

A cigar mold inside El Rey de Los Habanos, My Father Cigars' Florida cigar factory. (Photo/Jeffery Salter)

Oklahoma

Ultimo Cigar Factory (https://www.ultimocigars.com/)

Texas

Bobalu Cigar Co. (https://www.bobalu.com/), *Austin*

El Cubano Cigar Factory (http://www.elcubanocigars.com/), *Houston*

House of Cigars (http://houseofcigarsinc.com/), *Dallas*

Washington

San Juan Cigar Co. (http://www.sanjuancigars.com/)

West Virginia

Stoney Creek Cigars (https://stoneycreekcigars.com/)

Know of any cigar factories in the United States that you don't see here? Feel free to add it in our comments section.

Smaller U.S. Cigar Factories Team Up To Create New Political Coalition

MARCH 15, 2019 | By Andrew Nagy (/author/andrew-nagy)

A worker at El Titan de Bronze, a boutique cigar factory and shop located in Miami's Little Havana neighborhood.

Thirty-six boutique, handmade cigar manufacturers from 16 states have teamed up with the Cigar Rights of America to form the Coalition of American Cigar Rollers, a new organization that plans to advocate against regulations that threaten their businesses.

The formation of the new coalition was inspired by an article that appeared on this website called 50 Factories In The U.S. That Still Make Cigars (https://www.cigaraficionado.com/articles/50-factories-in-the-u-s-that-still-make-cigars). The group plans to brief state governors and local lawmakers on the negative consequences that strict FDA regulations will have on smaller handmade cigar manufacturers. Additionally, the coalition will engages their customers to join the fight against federal regulation of premium cigars.

The group will be led by two national co-chairs: Danny Difabio, owner of the Rodriguez Cigar Factory (http://rodriguezcigarskeywest.com/) in Key West, Florida, and Sandy Cobas, owner of El Titan de Bronze (https://titandebronze.com/) cigars in Miami, Florida.

"I hope that we can do our part to bring attention to the impact these regulations will have on women- and minority-owned businesses," said Cobas in a press release. "Each of us in this coalition are small, family-owned businesses. To confront the paperwork, expense, and time of these regulations is simply too much for many in this industry. We will each do our part to carry that message."

Many well-known brands are rolled at El Titan de Bronze, including La Colmena (https://www.cigaraficionado.com/ratings/search?brand=La+Colmena&main-search=main+search&submitted=Y) from Warped Cigars, Hererra Esteli Miami (https://www.cigaraficionado.com/ratings/search?submitted=Y&brand=Herrera+Esteli+Miami&submit-search=&text_search_flag=everything&fuzzy=no&submitted=Y&page=1&sort_dir=default&taste_date=&issue_date=&issue_year=&source=cigarsearch), Cornelius & Anthony (https://www.cigaraficionado.com/ratings/search?submitted=Y&brand=Cornelius+%26+Anthony&submit-search=&text_search_flag=everything&fuzzy=no&submitted=Y&page=1&sort_dir=default&taste_date=&issue_date=&issue_year=&source=cigarsearch), and La Palina's Goldie (https://www.cigaraficionado.com/ratings/search?submitted=Y&brand=goldie&submit-search=&text_search_flag=everything&fuzzy=no&submitted=Y&page=1&sort_dir=default&taste_date=&issue_date=&issue_year=&source=cigarsearch), Mr. Sam (https://www.cigaraficionado.com/ratings/search?submitted=Y&brand=&submit-search=&text_search_flag=everything&fuzzy=no&submitted=Y&page=1&sort_dir=default&brands%5B%5D=La+Palina+Collection+Mr.+Sam&taste_date=&issue_date=&issue_year=) and Family Series lines (https://www.cigaraficionado.com/ratings/search?submitted=Y&brand=&text_search_flag=everything&fuzzy=no&submitted=Y&page=1&sort_dir=default&brands%5B%5D=La+Palina+Family+Series+Mia mi&taste_date=&issue_date=&issue_year=&submit-search=Search).

"This is an important new step. The *Cigar Aficionado* story brought national attention to our very presence, and the skilled artisans that we each employ. The cigars produced in our small factories are among the best in the world, and made in America," said Difabio. "That's our message to the President's Administration, Congress, our governors, and customers throughout the nation. We just want to continue this art form that has been passed down from generation to generation."

The coalition will continue to add members as outreach continues. If you'd like to add your business, contact Patrick Carr of the Cigar Rights of America via email at patrick.carr@cigarrights.org.

MORE IN LEGISLATION (/LEGISLATION)

Cigar Companies to Pay Higher FDA User Fees this Year

OCTOBER 2, 2018 | By David Clough (/author/david-clough)

The U.S. Food and Drug Administration wants more money from the cigar industry. The FDA has released its calculations for user fees that will be collected from cigar companies in fiscal year 2019, and the grand total has increased to $80 million, up from $68 million last year. (Every year the FDA collects user fees from domestic manufacturers and importers of tobacco products and uses the money to fund its ongoing tobacco regulation activities.)

The FDA collects user fees from six types, or classes, of tobacco companies—domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, pipe tobacco and cigars.

The cigar class, which includes handmade cigars as well as machine-made cigars, will pay 11.35 percent ($80 million) of FDA's total user fee demand for fiscal year 2019. In total, FDA seeks $712 million from all the tobacco classes combined, up from $672 million last year. (For more on how FDA calculates user fees for the cigar class, see FDA User Fees Mean More Costs For Cigar Companies (https://www.cigaraficionado.com/article/fda-user-fees-mean-more-costs-for-cigar-companies-18844).)

User fees are considered burdensome to cigar companies and drive up the cost of doing business. Higher user fees could potentially force cigar manufacturers and importers to raise their prices to deflect the cost, resulting in more expensive cigars for the consumer.

April 19, 2019

Office of Senator Marco Rubio
United States Senate
Washington, DC 20002

Submitted via e-mail to: mike_needham@rubio.senate.gov

Re: Statement to be Made a Part of the Record of the April 5, 2019 Field Hearing of the U.S. Senate Committee on Small Business & Entrepreneurship

Dear Sir or Madam:

SWI-DE, LLC d/b/a Drew Estate ("Drew Estate") is one of the leading manufacturers and sellers of handmade premium cigars in the United States. Drew Estate's handmade premium cigars are crafted by skilled artisans in Drew Estate's manufacturing facility in Esteli, Nicaragua and distributed by retailers throughout the United States. As a key stakeholder in the premium cigar market, Drew Estate is not only directly impacted by the implementation of cigar regulations, but it is also intimately familiar with the individuals and small businesses at every level of the premium cigar industry – from manufacturers to distributors to thousands of "Mom & Pop" retailers -- that stand to be dramatically impacted by what can only be described as ill conceived, procedurally flawed, and stunningly overreaching FDA regulation. As such, Drew Estate submits this Statement, including the accompanying Appendices, in support of Senator Marco Rubio's Senate Bill S. 9, *The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act* and to be made a part of the record of the April 5, 2019 Field Hearing of the U.S. Senate Committee on Small Business and Entrepreneurship held in Tampa Bay, Florida.

FDA's current regulation of premium cigars, which negatively impacts small businesses across the nation, fails to pass any rational benefit-cost test and is built upon a series of unfounded presumptions that not only ignore, but are resoundingly contradicted by the government's own empirical research data. Senator Rubio's Bill S.9, on the other hand, is unequivocally supported by the best available scientific, economic, and public health data, and it is the ***only*** bill in Congress that properly seeks to protect premium cigar consumers and the small businesses that sell to them from unnecessarily burdensome agency regulation.

It is important to note that Representatives Kathy Castor and Bill Posey, have introduced a bill in the House of Representatives that, while also seeking premium cigar exemption, provides a narrower scope of exemption for premium cigars, excluding from the exemption any premium cigars with a flavor other than tobacco. In support of their proposed legislation, Representatives Castor and Posey sent a "Dear Colleague" letter, to other members of the House of Representatives, in which they relied upon information provided by FDA in Draft Guidance published on March 14, 2019 (the "Draft Guidance") regarding youth usage of flavored cigars as support for their determination to exclude premium cigars with a flavor other than tobacco from their proposed premium cigar exemption legislation. FDA's assertions in the Draft Guidance about youth usage are so demonstrably false and misleading as relates to premium cigars that Representatives Castor and Posey were relying in good faith on what, in fact, can only be properly described as FDA "misguidance." Senator Rubio's bill, like similar bills previously supported by Reps. Castor and Posey, properly supports small business by avoiding FDA's misguidance and calling for the exemption of ***all*** premium cigars, without regard to flavor, a position consistent with all available scientific, empirical and public health data.

CORPORATE OFFICES:
12415 SW 136TH AVE, SUITE 7, MIAMI, FLORIDA 33186
V. 786.581.1800 F. 786.581.1810 W. WWW.DREWESTATE.COM

I. Executive Summary

Through issuance of a final rule on May 10, 2016 (the "Deeming Rule)[1], FDA deemed all cigars sold in the United States to be subject to the Family Smoking Prevention and Tobacco Control Act (the "TCA"), a law originally enacted by Congress in 2009 to regulate cigarettes. In both its decision to include cigars within the purview of the Deeming Rule and subsequent decisions about how to exercise its regulatory discretion under the TCA, FDA has regrettably taken a "one-size-fits-all" approach to regulation, choosing to treat all tobacco products like cigarettes despite overwhelming evidence of material distinctions in tobacco product classes. FDA's regulations and conduct are particularly inexplicable as relates to premium cigars, an extremely small subset of the broader cigar category that is comprised of handmade, artisanal products with materially distinct consumers and usage patterns from all other tobacco products, which at every level from manufacturing to distribution to retail sale primarily at "Mom & Pop" shops, supports thousands of small businesses and tens of thousands of jobs across the nation

Drew Estate has strenuously advocated for the full exemption of premium cigars from current FDA regulation, including through its affiliation with Cigar Association of America, Inc. ("CAA"), the leading trade association of the cigar industry. On July 25, 2018, CAA filed a Comment with FDA (the "CAA Comment") in response to an FDA Advance Notice of Proposed Rulemaking related to the regulation of premium cigars (the "Premium ANPRM"). In the CAA Comment, a full copy of which including exhibits is attached as Appendix A, CAA set forth in exhaustive detail empirical data showing unequivocally that every stated reason upon which FDA made its determination not to exempt premium cigars is entirely without merit and is, in fact, in total and complete conflict with FDA's own research data.

In requesting comments on the Premium ANPRM (with respect to which FDA has yet to take any further action), FDA specifically sought new information not available in 2014 (when comments were submitted on the proposed Deeming Rule) that might cause FDA to reach a different conclusion than it had when it first decided not to exempt premium cigars from the Deeming Rule. By definition, this required looking back at FDA's stated rationale for reaching its original conclusion in 2016. In support of its original determination not to exempt premium cigars from the Deeming Rule, FDA concluded "that deeming all cigars, rather than a subset, more completely protects the public health."[2] FDA expressly based this finding on the following stated rationales: "(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults."[3] As set forth in CAA's Comment, abundant data had in fact become available since 2014 that challenged these conclusions, including, but not limited to, published findings from Waves 1, 2 and 3 of the Population Assessment of Tobacco and Health ("PATH") Study.[4]

The PATH Study, which was commissioned by FDA and conducted in coordination with the National Institutes of Health, is a longitudinal study that has followed over 45,000 subjects over the course of years to determine patterns

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[1] Final Rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81. Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule").

[2] *Id.* at 29,020

[3] *Id.*

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

of use of tobacco products. The PATH Study represents the most comprehensive study ever conducted of tobacco usage in the United States and is structured to provide results that are representative of tobacco usage patterns of the entire U.S. population ages 12 and above. To accomplish this, the PATH Study, identified the types of tobacco products used by study participants, which included premium cigars *of all types, both flavored and unflavored*. To date, the published results of the PATH Study include the findings from Waves 1, 2, and 3.[5] With respect to the usage patterns of *all* premium cigars , *including both flavored and unflavored premium cigars*, used by the study participants, the data across all three Waves is unequivocal and yields these incontrovertible conclusions: (i) youth usage of premium cigars is virtually non-existent; (ii) premium cigars are neither a gateway to initiation of use of other tobacco products nor an alternative source of nicotine for users of other tobacco products; and (iii) the usage patterns of premium cigar smokers sufficiently reduce health risks to warrant exclusion. Said more succinctly, and as set forth in more detail below, FDA's own research data rejects every stated basis upon which FDA has determined to regulate premium cigars.

The availability of usage pattern data from the PATH Study also enabled analysis of existing medical research to evaluate impacts of premium cigar use to the public health. As set forth more fully below, such analysis proves that impact to the public health of premium cigar use in the United States is, at most, de minimis. On the other hand, the cost of FDA regulation of premium cigars is enormous. Indeed, even based on its own estimates (which are generally considered to be too low), FDA has expressly stated that the cost of compliance with FDA regulation of premium cigars will be so extensive as to force many businesses, in particular small businesses, out of business altogether, putting at risk tens of thousands of jobs.

Stated very simply, the available data is unequivocal, any benefit to the public health from FDA's regulation of premium cigars will at best be negligible, and it will come at an extraordinary cost -- to the government, to consumers, and to businesses, in particular small businesses, across the country.

Given the abundance of data available to FDA, one cannot help but ask why FDA continues to assert positions that are flatly contradicted by the science. Given that FDA is populated by extremely bright and accomplished professionals and skilled empiricists across many disciplines – physicians, scientists, economists, to name a few -- one is almost invariably left with no other conclusion than that FDA made up its mind quite some time ago to ignore any factual distinctions between product classes and adopt a one-size-fits-all regulatory approach with the goal of eradicating all tobacco products in the United States, no matter the cost, including the livelihoods of tens if not hundreds of thousands of citizens across the country.

With respect to premium cigars, the contradictions are so extraordinarily glaring that Senator Rubio accurately noted at the April 5th Field Hearing that FDA's regulation of premium cigars is something "that everybody knows is wrong," and yet it is still happening.

II. FDA's PATH Data Rejects Every FDA Assertion Regarding Premium Cigars

FDA commissioned and has available to it the results of the most comprehensive study in history of tobacco usage patterns in the United States. This PATH Study data is referred to and relied upon frequently by FDA in other contexts, such as with respect to cigarette and e-cigarette usage patterns, when consistent with FDA's positions. With respect to premium cigars, however, FDA continues to assert positions that are completely at odds with its own

[5] The first wave of data collection began in September 2013 and was completed in December 2014 ("Wave 1"), the second wave of data collection began in October 2014 and was completed in October 2015 ("Wave 2"), and the third wave of data collection began in October 2015 and was completed in October 2016 (and released in May 2018) ("Wave 3").

research findings.

A. Youth Usage of Premium Cigars is Virtually Non-Existent

FDA has consistently made regulatory decisions on the presumption (unsupported by any cited data) that premium cigars are used by youth. In the most recent example, in its Draft Guidance published March 14, 2019, FDA once again concluded (without any reference to data) that cigars, and in particular flavored cigars, including premium cigars, present a risk of youth usage. The logic FDA appears to have employed in its Draft Guidance is that if youth are using flavored e-cigarettes and vapor products, then flavors (rather than e-cigarettes or vapor products themselves) must inherently be the problem, and all products with flavor must therefore inherently be used by youth. On its face, this logic is horribly flawed. When viewed in light of the actual data that FDA has in hand, FDA's continued assertions strain credulity.

1. As of the most recently published data from Wave 3 of the PATH Study, the prevalence of youth usage (ages 12 to 17) of premium cigars in the United States – which includes all premium cigars used by participants – *meaning both flavored and unflavored cigars* -- is 0.02% (i.e., two one-hundredths of one percent).

2. Across all three Waves of the PATH Study, prevalence of youth usage of premium cigars in the United States is less than one-tenth of one percent, and has been steadily declining in each Wave, from 0.08% in Wave 1, to 0.04% in Wave 2, to 0.02% in Wave 3.

3. In all three Waves, the prevalence of premium cigar use by youth ages 12 to 14 is 0.00%.

There is simply no explanation for FDA's continued assertions regarding youth usage of premium cigars. FDA's data is unequivocal. Youth usage of all premium cigars, *including both flavored and unflavored premium cigars*, is virtually non-existent. In light of the data, one is hard pressed to reach a conclusion other than that FDA has purposefully ignored (and failed to inform Congress or the public about) valid scientific data that is inconsistent with FDA's agenda to overstep its Congressional mandate under the TCA and eradicate legal tobacco use in the United States. The pernicious effects of this FDA misguidance can be immediately seen in the reliance that Representatives Castor and Posey in good faith placed on the information published by FDA in its Draft Guidance -- information that is simply untrue.

B. Premium Cigars are Neither a Pathway of Initiation or Progression for Youth or Young Adults

Given the virtually non-existent youth usage rate of premium cigars, it is effectively impossible for premium cigars to serve as a pathway of initiation to tobacco products or progression to use of other tobacco products, such as cigarettes, a product category where meaningful youth usage and significant public health risks have been documented by FDA. Not surprisingly, the PATH Study resoundingly contradicts FDA's unfounded presumptions regarding premium cigars as either a pathway of initiation to tobacco usage or a pathway of progression to use of other tobacco products, in particular cigarettes. It bears repeating that the PATH Study evaluates use of all premium cigar products, including both flavored and unflavored premium cigars, used by participants, and the PATH Study data results with respect to usage of all premium cigars is as follows.

1. As of Wave 3 of the PATH Study, the median age of initiation for regular use of premium cigars is 30.0 years of age, having steadily risen from already high medians of 24.8 years of age in Wave 1 and 27.6 years of age in Wave 2.

2. The percentage of premium cigar smokers, of any age, in the PATH Study that progressed from never smoking cigarettes or smoking cigarettes some days in Wave 1 to *"everyday"* cigarette smoking in Wave 3 is 2.2%, which is statistically indistinguishable from the rate at which participants that were non-smokers in Wave 1 became everyday cigarette smokers over the same period.

3. Similarly, the percentage of premium cigar smokers, of any age, in the PATH Study that progressed from never smoking cigarettes or smoking cigarettes some days in Wave 1 to *"some day"* cigarette smoking in Wave 3 is 5.9%, which is likewise statistically indistinguishable from the rate at which participants that were non-smokers in Wave 1 became some day cigarette smokers over the same period.

4. Finally, among premium cigars users in Waves 1, 2 and 3 of the PATH Study, those who also smoke cigarettes do not smoke more premium cigars than premium cigar users that do not smoke cigarettes (as set forth more fully below, both groups' usage rates are best described as very occasional). Said differently, the data does not support that cigarette users are using premium cigars as an alternate source of nicotine.

Again, the facts belie FDA's continued, unfounded assertions that premium cigars are either a gateway of initiation or progression. The data is unequivocal: (i) premium cigars – of all kinds -- are used only by adults, who do not begin regular usage until they are well into adulthood; (ii) premium cigar users – of all kinds -- are no more likely to progress into becoming "everyday" or "some day" cigarette smokers than non-smokers; and (iii) cigarette smokers do not progress to use of premium cigars – of any kind -- as an alternative source of nicotine. FDA is simply spreading fake news.

C. Premium Cigar User Demographics Do Not Support FDA Regulation

FDA has repeatedly asserted that tobacco products are used by those that are young, less educated and less economically affluent and that evidence does not support that premium cigar users are differently situated. The demographic data from the PATH Study for adult users of all premium cigars proves otherwise. The data demonstrates that premium cigars are used by adults that are older, better educated, and more affluent.

1. **Age:** As of Wave 3 of the PATH Study, 67.0% of premium cigars users are age 35 or older and 90.6% were age 25 or older. These averages are consistent with and build upon the already high averages in Waves 1 and 2:

    - In Wave 1, 57.2% of premium cigar users were age 35 or older and 83.8% age 25 or older; and

    - In Wave 2, 61.9% of premium cigar users were age 35 or older and 87.6% age 25 or older.

2. **Education:** As of Wave 3 of the PATH Study, 83.3% of premium cigar users aged 25 and over had some level of higher education, with 52.7% having completed college and an additional 30.6% having either completed some college or associate degree program. These averages are consistent with and build upon the already high averages in Waves 1 and 2:

- In Wave 1, 78.1% of premium cigar users had some level of higher education (44.9% having completed college and an additional 33.2% having either completed some college or associate degree program), and

- In Wave 2, 80.5% of premium cigar users had some level of higher education (49.1% having completed college and an additional 31.4% having either completed some college or associate degree program).

3. **Household Income.** As of Wave 3 of the PATH Study, 72.8% of premium cigar users have household income of at least $50,000 - $99,000 per year, 43.9% have household income of at least $100,000 - $199,999 per year, and 15.0% have household income of $200,000 or more per year. Again, these averages are consistent with and build upon the already high averages in Waves 1 and 2:

   - In Wave 1, 64.4 of premium cigar users had household income of at least $50,000 - $99,000 per year, 35.5% had household income of at least $100,000 - $199,999 per year, and 11.0% had household income of $200,000 or more per year; and

   - In Wave 2, 67.6 % of premium cigar users had household income of at least $50,000 - $99,000 per year, 35.6% had household income of at least $100,000 - $199,999 per year, and 10.2% had household income of $200,000 or more per year.

FDA continually seeks support for its onerous regulation of premium cigars by creating the spectre of a product that is used by the young, the less educated and the less affluent. FDA's assertions are demonstrably false on every count. Premium cigars of all types – both flavored and unflavored -- are used by older, better educated, and more affluent adults.

D. Usage Patterns of Premium Cigars Are Sufficiently Different to Support Exemption

A scientific research study was not necessary to inform anyone that premium cigars are luxury items used almost exclusively on rare occasions to celebrate an event or to enjoy a momentary respite from a fast-paced world. Albeit not necessary, the PATH Study data proves exactly that.

1. **Incredibly Small Niche Market.** As of Wave 3 of the PATH Study, only **0.53% of the overall adult population** uses premium cigars. This is consistent with Wave 1 (0.56%) and Wave 2 (0.58%), and is about 4 times less than the prevalence of non-premium cigar usage and almost 35 times less the prevalence of cigarette usage.

2. **Extremely Low Monthly Use.** The median monthly usage of premium cigars is **1.3 days per month** as of Wave 3 of the PATH Study, which is consistent with the already low medians of 1.7 days per month in Wave 1 and 1.4 days per month in Wave 2. This is over 3 times lower than for non-premium cigars and over 22 times lower than for cigarettes (which has median monthly usage of 29.4 days per in each of Waves 1, 2 and 3).

3. **Extremely Low "Per Day" Use.** The median number of cigars smoked per day by premium cigar users in a monthly period is **0.1 premium cigars per day** in each of Waves 1, 2, and 3. This is about half as much as for non-premium cigar use and 99 times less than for cigarette use (the median for which is 9.9 cigarettes per day as of Wave 3).

4. **"Less Than Daily" Use.** As of Wave 3 of the PATH Study, **96.1% of premium cigars users smoke premium cigars on a *less than daily* basis**. This is consistent with Waves 1 and 2, where 93.5% and 92.5% of premium cigar users smoke premium cigars less than daily, and reflects 18% higher non-daily use than for non-premium cigars and over 63% higher non-daily use than for cigarettes (where 77% of users smoke cigarettes on a daily basis).

Given that FDA's PATH Study data shows that only 0.53% of the population uses premium cigars of any kind and that only 3.9% of that small niche market smokes premium cigars on a daily basis, Senator Rubio was accurate in stating at the Field Hearing on April 5, 2019, that we are talking about "a sliver of a sliver" when it comes to any premium cigar use in excess of "less than daily" usage. As discussed below, this PATH Study premium cigar usage pattern data so dramatically affects the analysis of any potential impact to public health that the burden of FDA regulation simply cannot be justified in view of the de miminis benefit.

III. The Impact of Premium Cigar Use to the Public Health is De Minimis

FDA has expressly stated that its original decision not to exempt premium cigars from regulation was based in part on FDA's conclusion that "the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion."[6] The PATH Study usage pattern data allows that presumption to be tested against the available medical research. The available medical research rebukes FDA's stated beliefs.

A. Analysis of Geoffrey Kabat, Ph.D M.S.

On July 24, 2018, Dr. Geoffrey Kabat authored a report, which was included as Exhibit C to the CAA Comment filed with FDA, the entirety of which (including Dr. Kabat's report) is incorporated as Appendix A to this Comment. In his report, Dr. Kabat analyzed the findings of the available medical studies of the health effects of cigar usage, including studies authored by FDA staff. Dr. Kabat's findings show that based on the known premium cigar usage patterns identified by FDA in the PATH Study, there is de minimis risk posed to the U.S. public health by premium cigars. More precisely, Dr. Kabat concluded that the available research and epidemiological studies prove that:

1. Cigar smokers (premium or otherwise) who smoke cigars less than daily (which, as set forth above, includes 96.1% of premium cigar smokers) have no statistical difference in mortality rates as compared to non-smokers;

2. Cigar smokers (premium or otherwise) who smoke less than daily do not have an increased risk for smoking-related cancers or an increased risk of death from all causes and certain specific causes.

3. Non-daily premium cigar smokers have no increased health risks compared to non-smokers.

[6] Deeming Rule at 29,020.

B. Testimony of Brad Rodu, DDS

Dr. Brad Rodu, a Professor in the Department of Medicine and Endowed Chair, Tobacco Harm Reduction Research at the University of Louisville School of Medicine provided both live and written prepared testimony at the April 5, 2019 Field Hearing of the U.S. Senate Committee on Small Business & Entrepreneurship, which are a part of the hearing record. In his written prepared testimony, a copy of which is contained in Appendix B, Dr. Rodu likewise found that based on a review of the available medical research data and the known usage patterns of premium cigar users that premium cigar use presents "minimal to no adverse health effects" and that regulation of premium cigars "will have negligible impact on the public health."

Given that Dr. Rodu's testimony, both oral and written, is already a part of the hearing record, no attempt will be made here to recite or review the abundant medical research studies that he evaluated. In terms of his conclusions, Dr. Rodu focused on distinctions between combustible tobacco products that are typically inhaled (such as cigarettes) and those that are not (such as cigars) and found that upon an examination of the available medical research, including studies authored by FDA Staff, the evidence shows:

1. Smoking 1 to 2 cigars per day has minimal to no risks related to mortality for all causes of death.

2. For men who smoke 1 to 2 cigars per day, there are "no significantly elevated risks for death from coronary heart disease, stroke or emphysema, which are three big killers for cigarette smokers."

3. Non-daily cigar users (again 96.1% of premium cigar users) have no elevated mortality risks as compared to non-smokers.

4. Consumption of up to two cigars per day is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.

It is a different set of underlying studies, but the story is the same. FDA is basing its conclusions on conjecture and hyperbole rather than fact. It is fake news. It is regrettable that FDA is taking a one-size-fits-all approach to its regulations. It is unconscionable that FDA is taking a one-size-fits-all approach to its facts. The fact that cigarettes or e-cigarettes may have elevated youth usage rates, does not mean that cigars have elevated youth usage rates. The fact that cigarette smoking may create significant disease and mortality risks, does not mean that cigars create the same risks. Indeed, the science tells us otherwise; a fact FDA is not telling anyone.

IV. The Costs of FDA Regulation of Premium Cigars are Unjustifiably Overwhelming

In view of the fact that any benefits to the public health that could conceivably result from FDA's regulation of premium cigars are almost imperceptible, it is difficult to justify any significant use of government and private resources in support of such regulation. The costs of compliance with FDA regulation of premium cigars – whether based on FDA's cost estimates (which are unquestionably low) or industry's estimates (which are significantly higher) – will cause premium cigar brands and premium cigar manufacturing businesses, particularly small businesses, to exit the marketplace. FDA has expressly stated as much. In addition to being unable to present any meaningful, fact-based justification for this burden on the economy, FDA has also failed to meet its legal obligation to determine whether any alternatives exist that might reduce these unnecessary economic impacts for small business.

A. The Premium Cigar Industry is the Definition of a Low-Volume, Small Business Industry

The premium cigar industry is comprised primarily of small businesses, including over 50 domestic manufacturers and approximately 3,000 "Mom & Pop" retail stores across the country.[7] It is estimated that these businesses directly support over 37,000 jobs. Many of these are family run businesses that have been passed down from one generation to the next, and all of these small businesses serve the tiny niche market of discerning adult consumers that appreciate the occasional experience of enjoying a fine, handmade product. Indeed, it is the very nature of these artisanal products and the discerning tastes of the adult consumers who demand them that make FDA regulation particularly destructive to small businesses in the premium cigar industry.

A discussion of the costs of compliance with FDA regulation of premium cigars must necessarily begin with an understanding of the nature of these artisanal, handmade products; both in terms of production and consumer demand in the marketplace. From a production standpoint, premium cigar manufacturing follows the centuries old tradition of taking natural tobacco leaves (the "filler"), wrapping those leaves in another natural tobacco leaf (the "binder") and then wrapping the binder and filler together in another tobacco leaf (the "wrapper"). This is entirely unlike the mass production of cigarettes upon which FDA's regulatory scheme was built, where enormous quantities of tobacco are processed and blended together to achieve a homogenized blend that can be run through machines that produce cigarettes by the millions. By using individual tobacco leaves, premium cigars are imbued with the natural variation of any agricultural product, with the terroir, the weather conditions, and the portion of the individual leaf used each imparting natural variation that lends to the delicate nuances that are a large part of the enjoyment of any artisanal product. Similarly, given that each step of making a cigar – cutting, binding and wrapping – is done by hand, each premium cigar has the slight, but unique, variations of any handmade product. Do these variations change the fundamental nature of each cigar from the next one in the box? Of course not. Do these variations appeal to the cerebral nature of the users of premium cigars, who derive much of the enjoyment of their occasional cigars from contemplating the unique nature of these nuances? Certainly. Do these variations make it incredibly difficult (and incredibly costly) to comply with a set of regulations that was created for totally homogenized cigarette products that are identically spun off machines by the millions. Unquestionably.

The costs of compliance with FDA regulation is even more burdensome for small businesses in the premium cigar industry as compared to the behemoth cigarette manufacturers for whom the regulations were created due to the incredible breadth of low volume premium cigar products of various size, shape, and blend. Premium cigar smoking is typically not an everyday activity. It is an occasional luxury, and like all luxuries a significant part of the enjoyment is the experience itself. These are fanciful products, and like drinking a mixologist's cocktail or eating at a fine dining restaurant, adult consumers think, "I don't get to do this all the time, let me try something new and interesting." The experience driven premium cigar consumer demands variety.

Unlike the multi-billon dollar cigarette market, which has only a dozen or so leading brands and somewhere between 100 and 200 variations of products across the entire product class, the niche premium cigar market is estimated to include anywhere from 10,000 to 20,000 unique products. For example, Drew Estate alone has over 3,000 SKUs in its product portfolio. Similarly, five online retailers surveyed as part of the Econsult Report submitted with the CAA Comment (and included in Appedix A) each offered on average approximately 10,000 unique

[7] *See Prepared Testimony of Charles Maresca, Director of Interagency Affairs, Office of Advocacy, U.S. Small Business Administration*, submitted on the record of the Field Hearing of the United States Senate Committee on Small Business and Entrepreneurship, April 5, 2019, Performing Arts Building Auditorium, Hillsborough Community College, Ybor City Campus, Tampa Bay, Florida ("Maresca Testimony") at 4 – 5.

premium cigar SKUs in 2017 alone.[8] Given the very small size of the marketplace versus the extensive number of unique products offered, premium cigar products are, generally speaking, low volume products. This is particularly true given the fanciful nature of the premium cigar experience, where adult consumers yearn for limited editions, seasonal products, single store-only blends, and similar limited availability products that appeal to the experience driven nature of enjoying a luxury item that is not available to everyone. Production of these low volume, "special" artisanal products, which represent a core component of the premium cigar industry, would effectively be impossible in the face of the cost of compliance with an FDA regulatory scheme that was designed for a small set of incredibly high-volume cigarette products. Said differently, small businesses in the niche premium cigar industry are being unduly forced to shoulder a far greater burden than the massive cigarette companies for which these regulations were created.

To compound this problem, the predicate date set for cigars under the Deeming Rule requires substantial equivalency filings for products going back nine years from the effective date of the rule, as compared to cigarettes, where substantial equivalency showings were only required for products brought to market in the *two years* prior to the initiation of FDA's regulatory scheme under the TCA. As a result, FDA's regulatory scheme places far more burdens and costs on the small premium cigar businesses that represent a class of products that 0.53% of the population consume barely once a month than on the enormous corporations that make and sell cigarettes, which are smoked by nearly 34 million Americans every day.[9] This unjustifiable assault on small business is an inexplicable waste of government and private resources.

B. The Cost of Compliance

For a small business cigar manufacturer, FDA estimates compliance costs to be $278,000 to $397,000 in the first year, $292,000 to $411,000 in the second year, and $235,000 to $257,000 in the third year.[10] FDA's estimates are woefully deficient. FDA admits to excluding unquantified costs attributable to the final rule, including the following: consumer costs due to loss of product variety or potentially higher prices; costs for testing for harmful or potentially harmful constituents; costs for clinical testing to support substantial equivalence reports; market adjustment and exit, and more.[11] In addition, FDA severely underestimated the number of products that the Deeming Rule would cover, estimating a baseline of 7,500 cigar products subject to the rule, 4,500 of which would be grandfathered (and thus not require pre-market review), 2,625 of which would be submitted for premarket review and 375 of which would exist the market.[12] As discussed above, and based on comments submitted to FDA, these estimates were highly inaccurate.[13] By severely underestimating the volume of products in the industry, it also means that any cost estimates FDA presented were woefully inadequate. Furthermore, FDA estimated the cost of each initial Substantial Equivalence Report to be $22,787,[14] which is likewise an extremely low estimate. By way of comparison, CAA member companies estimate that each SE Report may cost a minimum of $250,000.[15]

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[8] Econsult Report at 21 & tbl. 3 (attached hereto as Exhibit B to CAA Comment)
[9] NERA Report at tbl. 2 and tbls. 4a-c.
[10] *Deeming Tobacco Products to be Subject to the Food, Drug and Cosmetic Act: Final Regulatory Impact Analysis* ("FRIA") at 133, *available at* https://www.regulations.gov/document?D=FDA-2014-N-0189-83196.
[11] *Id.* at 7.
[12] *Id.* at 85.
[13] *Comment Letter from Cigar Association of America, Inc. to FDA Division of Dockets Management re: Docket No. FDA-2017-N-5095* (Feb 5, 2018), at 14, *available at* https://www.regulations.gov/contentStreamer?documentId=FDA-2017-N-5095-0032&attachmentNumber=1&contentType=pdf.
[14] *Id.* at 17.
[15] *Id.*

Even accepting FDA's woefully insufficient cost estimates, *and without even considering the "unquantified" costs that FDA acknowledged excluding from its analysis*, the cost of compliance for small business in the premium cigar industry will be extremely damaging. After acknowledging that 90% of the domestic entities affected by the Deeming Rule are estimated to be small businesses[16], FDA casually observed, "some firms may exit the market."[17] When realistic costs are applied, the damage to small businesses will be disastrous.

Beyond the *direct* damage to small businesses from these compliance costs, small businesses will be hurt even further by the damage these costs will cause to the larger businesses that serve them. Even as the third largest manufacturer and seller of premium cigars in the United States, Drew Estate is unable to bear the per-product compliance costs of FDA regulation. As noted above, whether it is Drew Estate, another manufacturer, or one of the many Mom & Pop retail shops across the country, all participants in the premium cigar industry ultimately provide goods and services to a highly educated group of discerning adult consumers that demand variety in their premium cigar choices. In addition to the constraints of handmade production and the small overall market size, this consumer demand for choice is what drives premium cigar product portfolios that are largely comprised of incredibly low volume SKUs.

By way of example only, Drew Estate manufactures a number of specific products each of which is sold only to one retailer, so the adult customers of those retailers who appreciate such things can know that at their local store they can purchase something that is not available anywhere else. These products are not just low volume, they are extremely low volume. Products like these, and many similar limited production products, are essential to adult consumers that frequent small retail establishments because it speaks to the sensibilities of educated, discerning adult consumers that are looking for something special to enjoy as an occasional, joyful luxury. Under existing FDA regulation, all such low volume products, which account for a significant number of SKU's in Drew Estate's portfolio, would disappear, as would the consumer choice that adult customers of small retailers across the country have come to expect. FDA has openly projected that such product consolidation would result from their regulations. What FDA has failed to explain is what purpose this serves. Given that the data proves that the current extensive array of unique premium cigar products in the market are not used by youth and pose no significant risk to the public health, what benefit is gained by having a vastly smaller group of premium cigar products that are likewise not used by youth or posing significant risk to the public health? The answer is that there is no benefit. But, there is a result. The result is that small businesses will be damaged, and many will go out of business. And why? Because in FDA's view any action that removes a tobacco product from the market is a good action and any action that removes a tobacco business from the market is a good action.

The same abusive disregard for fact and legally mandated process can be seen in FDA's recent Draft Guidance related to flavors. As noted above, in reaction to elevated youth usage rates of *e-cigarettes and vapor products*, FDA without hesitation (or analysis) decided that the solution was to revise its enforcement actions in a manner that would effectively result in the removal of most flavored *cigars* from the marketplace. In its Draft Guidance, FDA offered neither any evidence nor any rationale supporting the notion that cigars of any kind have had or could have any impact on the rate of youth usage of e-cigarettes or vapor products. Rather, FDA felt comfortable proposing an action that would massively damage businesses large and small on the *assumed possibility* that if youth usage rates of e-cigarettes and vapor products, many of which are flavored, were successfully reduced then youth *might possibly* decide to start using flavored cigars instead. In point of fact, according to the 2018 National Youth Tobacco Survey, the 2017 Youth Risk Behavior Surveillance System, and the 2016 National Survey on Drug Use and Health, youth

[16] *See* Maresca Testimony at Appendix 1, p.3
[17] FRIA at 133.

usage of *all* cigars (including non-premium cigars) has been significantly declining for years, and as discussed above, the PATH Study shows unequivocally that for premium cigars, in particular, youth usage is essentially non-existent. In failing to evaluate available data and instead initiating a regulatory action with major impacts to adult consumers and businesses large and small across the country on the basis of pure guesswork as to what might possibly happen (or not), FDA failed to meet its legal obligations. Like it has in the past, FDA appears to assume that when it comes to tobacco products of any kind, it can simply regulate without oversight, without reason, and without any assessment of the costs to small businesses or anyone else.

C. FDA Failed to Consider Alternatives or Properly Measure Benefits and Costs

Under the Regulatory Flexibility Act, FDA was required in proposing the Deeming Rule to submit an Initial Regulatory Flexibility Analysis ("IRFA") including, among other things, "a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact of the proposed rule on small entities."[18] As set forth in the prepared testimony of Charles Maresca, Director of Interagency Affairs, Office of Advocacy, U.S. Small Business Administration, at the April 5, 2019 Field Hearing in Tampa, after reviewing FDA's IRFA for the proposed Deeming Rule, the SBA Office of Advocacy submitted a comment letter to FDA, on June 11, 2014, stating that "FDA's IRFA was deficient because it neither adequately: (1) described the impacts on all of the types of newly covered small entities, nor (2) explained significant alternatives that might reduce those impacts."[19] Advocacy suggested in its comment letter that FDA publish a Supplemental IRFA for public comment prior to proceeding to a final Deeming Rule, but FDA did not do so.[20] Instead, FDA ignored the SBA Office of Advocacy's finding that FDA's IRFA, "does not set forth, consider and discuss significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities."[21]

This is not surprising, considering FDA's failure to adequately measure either benefits or costs associated with its proposed regulation, as required by law. Pursuant to Executive Order 12866, "Each agency shall assess both the costs and benefits of the intended regulation and . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[22] This principal was reaffirmed in Executive Oder 13563, which stated that "each agency . . . must propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs . . . ."[23]

In its Final Regulatory Impact Analysis related to the Deeming Rule, FDA repeatedly states that it "cannot quantify the benefits of the final rule."[24] FDA went on to state that "[r]eliable evidence on the impacts of warning labels, premarket review, and marketing restrictions on users of cigars . . . does not, to our knowledge exist."[25] FDA admits that it has no knowledge of the impacts of its regulatory efforts and cannot quantify the benefits of its final Deeming Rule. This certainly cannot serve as the basis for a "reasoned determination," particularly when, as here, the costs are so substantial.

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[18] 5 U.S.C. § 603 (2019)
[19] Maresca Testimony at 3.
[20] *Id.*
[21] *Id.* at Appendix 1, p. 6.
[22] Exec. Order No. 12, 866, 58 Fed. Reg. 735 (Oct. 4, 1993)
[23] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011)
[24] *See* FRIA at 67.
[25] *Id.*

Even after acknowledging deficiencies in its cost estimates, such as underestimating the volume of cigars that would be regulated by the Deeming Rule,[26] FDA bluntly stated with regard to market exit:

> Some manufacturers and importers may cease to sell products in the U.S. rather than bear the cost of complying with this final rule. In particular some low-volume cigar . . . manufacturers may cease to offer their products in the U.S.[27]
>
> "....products with low sales volume, products with small-batch production runs, and low-volume products sold only in specialty retail outlets and other channels. We expect such product will exit the market as a result of this rule."[28]
>
> It may not be profitable for firms to bear the per-product costs of this final rule for all products currently marketed . . . . Our analysis reflects a significant degree of product exist and consolidation.[29]

The foregoing statements could not more aptly describe the premium cigar industry; an industry of low volume, handmade, artisanal products, manufactured and sold by small, often family-run, businesses. An industry that, in FDA's own assessment, will not survive FDA regulation.

One has to ask how an agency could consider itself to have properly fulfilled its legal obligations to make reasoned determinations and evaluate significant alternatives when adopting a rule with no "quantifiable benefits" and a presumption of "a significant degree of product exit and consolidation" and manufacturers that "cease to offer their products." Based on FDA's actions, the answer seems apparent. FDA is beholden to a fundamental belief that all tobacco products have the same impacts to the public health as cigarettes, and thus no further analysis of the benefit of regulating such products needs to be undertaken and no cost of such regulation is too great. Facts be damned.

V. Conclusion

Despite FDA's desire to avoid them and its consistent pattern of not sharing them with the public at large, the facts here are known, and they are straightforward. There is effectively no youth usage of premium cigars of any kind, whether flavored or unflavored. Use of premium cigars neither leads to nor results from use of other tobacco products. The potential benefit to the public health of regulating premium cigars is *at best* de minimis. The cost, however, is enormous -- to government, to consumers, and to businesses large and small across the nation. There is simply no rationale under which the barely discernable benefit of FDA regulation of premium cigars can justify the cost. It is not even close.

Clearly, FDA has overreached in the zealously blind pursuit of its agenda to eradicate tobacco products, and it has not been held to account for having lost sight of its core purpose and mission – to wisely spend resources to protect the public health. Consequently, it is up to our three branches of government – Executive, Congress, and the Judiciary – to intervene in this matter.

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[26] *Id.* at 75.
[27] *Id.* at 70.
[28] *Id.* at 75.
[29] *Id. at* 78, 80.

Senator Rubio has recognized that the rights of the premium cigar industry and those of the hundreds of thousands of citizens who comprise this industry are improperly and unnecessarily under attack by overreaching FDA regulation. Never has the need for Senator Rubio's strong voice, and the voices of other members of both congressional chambers, been greater than it is today.

Drew Estate has and continues to strongly advocate for the full exemption of ***all*** premium cigars from FDA regulation. We fully support Senator Rubio's Bill S.9, which is the only pending legislation in Congress that truly gets it right. Supporting any positions other than those set forth in Senator Rubio's bill will be nothing less than tragic. Senator Rubio's bill is the only bill that will prevent damaging the livelihoods of small business owners and employees across America, thwart transgressions on the rights of discerning adult smokers to enjoy these wonderful artisanal products and arrest FDA's egregious attempt to regulate an industry based on conjecture and presumptions that are completely and overwhelmingly disproven by scientific fact.

Respectfully submitted,

Glenn C. Wolfson
Chief Executive Officer
Drew Estate

April 5, 2019

The Honorable Marco Rubio
Chairman
Senate Committee on Small Business & Entrepreneurship
428-A Russell Senate Office Building
Washington, DC 20510

The Honorable Ben Cardin
Ranking Member
Senate Committee on Small Business & Entrepreneurship
428-A Russell Senate Office Building
Washington, DC 20510

Dear Chairman Rubio and Ranking Member Cardin:

Today's field hearing "*Keeping Small, Premium Cigar Businesses Rolling,*" comes at a critical time for the American premium cigar industry. As you know, the Family Smoking Prevention & Tobacco Control Act was intended to prevent youth usage of tobacco products and address the negative health effects of smoking addiction. These serious public health concerns are not commonly found in government data concerning premium cigar use. Yet, through a very broad exercise of the U.S. Food & Drug Administration's (FDA) deeming authority, premium cigars were aggregated with mass produced tobacco products more commonly found in convenience stores. Today, premium cigars remain in this mismatched regulatory state at a tremendous risk to the small business and family owned companies that bring them to market.

Founded in 1933, the International Premium Cigar and Pipe Retailers (IPCPR) is a not-for-profit trade association representing over 3,000 specialty retail stores and more than 350 manufacturers, distributors and service providers to the industry. Our retailers employ an average of 5-6 employees per store. That is approximately 16,500 jobs nationwide that are at risk because of the current regulations on premium cigars. Our members are predominantly small businesses with close community ties that pride themselves on providing adults with knowledge of the vintage, terroir and culture of the artisanal products that are premium cigars. Unlike other tobacco products, a premium cigar takes 3–5 years from seed to sale, is handmade, and comprised only of three ingredients: 100% natural whole tobacco leaf, water and natural vegetable gum.

As an industry, we are encouraged by FDA's emphasis on data driven policymaking. Last year, FDA and NIH released "The Population Assessment of Tobacco and Health Study," a joint study that covered a multi-year cross section of youth and adults. Referred to by NIH as "one of the most important tobacco health studies ever," the study introduces incontrovertible evidence that the usage patterns of premium cigars are amongst older adults. The corresponding lack of use by youth and lack of evidence of nicotine addiction (or transference to cigarette smoking) point toward negligible public health risk and therefore warrant a different regulatory framework, if not exemption from the Tobacco Control Act.

In March of 2018, the FDA issued an advanced notice of proposed rulemaking to consider whether premium cigars should be regulated under their own unique framework from the broader cigar category. The cigar category currently includes products that are both mass produced and flavored. In response, IPCPR submitted comments outlining data generated from government-run studies on use of tobacco products including premium cigars. The data demonstrates clearly that the continuum for risk to public health is limited if not negligible:

- The average premium cigar consumer purchases their first premium cigar at age 30 (compared to age 16.7 for cigarettes)
- The average premium cigar smoker smokes 1.2/30 days (compared to 29.6/30 days for cigarettes).
- No statistically significant increase in risk for smoking related diseases was found between non-daily premium cigar smokers and non-smokers in general.

While we are hopeful that data driven policymaking will be the driving factor in this rulemaking, we have serious concerns for the small businesses, which constitute the majority of the premium cigar industry. Small businesses have limited capacity to absorb increased costs for regulatory compliance, FDA user fees, and to manage uncertainty over new regulations such as those that may impact packaging and component testing. The livelihood of our retailers is at risk and therefore just and timely correction is needed to shield them from irreparable harm.

Thank you again for raising this important matter before the Committee today. We hope that the insights gained will help to move towards a policy correction that will benefit the economy, and more importantly restore justice to thousands of small businesses producing and selling premium cigars.

Sincerely,

Scott Pearce
Executive Director
International Premium Cigar and Pipe Retailers

Rocky Patel Premium Cigars
10960 Harmony Park Drive
Bonita Springs, FL 34135

April 19, 2019

Kathyrn Eden
Senate Small Business Committee
Washington, DC

We wish to begin by thanking Chairman Rubio and the Senate Committee on Small Business and Entrepreneurship for the field hearing that was recently held in Tampa, Florida on Friday, April 5, 2019 entitled, "Keeping Small, Premium Cigar Businesses Rolling." Additionally, we wish to thank Representative Gus Bilirakis and Representative Kathy Castor for their participation as well as the panelists who participated in the hearing.

Rocky Patel Premium Cigars appreciates this opportunity to provide a statement for the hearing record that demonstrates the negative economic impacts that the Food and Drug Administration ("FDA") deeming regulation over premium cigars would inflict upon our company and the premium hand-rolled division at large.

Rocky Patel Premium Cigars is a global leader and one of the most recognized companies in the premium cigar industry. Rocky Patel Premium Cigars is currently headquartered in Bonita Springs, Florida, where the company maintains it operations and distribution networks. Internationally, Rocky Patel Premium Cigars has factories and tobacco fields in Honduras and Nicaragua that employ over 3,000 people in the artisan craft of premium cigar manufacturing. With annual production of 24 million premium cigars, Rocky Patel Premium Cigars is universally recognized as one of the largest producers of premium cigars in the world that is constantly expanding.

Additionally, Rocky Patel Premium Cigars operates a revolutionary brand of premium cigar lounges aptly named BURN. Currently, there are five locations across the United States, Naples, Atlanta, Oklahoma City, Indianapolis, and Pittsburgh.

On May 5, 2016, the FDA announced the release of its final rule on the Deeming of tobacco products as subject to the Agency's authority. FDA opted in the rule to extend its authority over premium cigars and to apply the same regulatory standards to those products as to all other deemed tobacco products.

At the time, Cigar Rights of America ("CRA"), a non profit association that advocates on behalf of the premium hand-rolled cigar industry was heartened to see that FDA was considering an exemption for premium cigars in its proposed rule, and that it was explicitly doing so on the grounds that premium cigars might pose a lower threshold of risk than some other tobacco products and are enjoyed only by adult consumers in

moderation. FDA requested comment from the public about this continuum of risk, and CRA was happy to provide detailed evidence to support it. (Copy of the CRA docket comment submission on August 8, 2014, (https://www.regulations.gov/searchResults?rpp=25&po=0&s=http%3A%2F%2Fwww.regulations.gov%2F%23!documentDetail%3BD%3DFDA-2014-N-0189-75924&fp=true&ns=true)
We believed that such an exemption was fully justified by the science and the evidence, and indeed, that it was required by the cost-benefit provisions of Executive Orders ("EO") 12866 and 13563.

The Deeming Regulation Misapplied the Correct Evidentiary Standard

It was, thus, surprising to see FDA opt in the final rule not to provide any exemption, significant flexibility, or meaningful regulatory relief. The Agency moved the goalposts in the final rule and, rather than proving its case that premium cigars should be regulated (as required by the EO's and the Administrative Procedures Act), shifted the burden of evidence to commenters to prove that premium products should not be regulated.

The FDA failed to meet the basic standard of rulemaking: it did not provide a coherent rationale for regulating premium cigars, and it has not demonstrated that the likely benefits of the regulation it has finalized will justify the costs. Instead it has adopted a precautionary principle and effectively declared that any hazard justifies full regulation, regardless of the impact on manufacturers. FDA admits that the studies upon which it relies to justify regulations do not differentiate between premium cigars and other products within the broad cigar category. In fact, the authors of one study FDA cites specifically conclude ""Data 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."

On March 23, 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) to seek comments and scientific data related to the patterns of use and resulting public health impacts from what are often referred to as "premium" cigars to inform the agency's regulatory policies. CRA submitted comments that chronicle new, compelling FDA financed studies based upon the PATH longitudinal study that further demonstrate our claim that premium cigars do not possess a youth access, initiation, and usage risk (https://www.regulations.gov/document?D=FDA-2017-N-6107-0001). It is worth noting that youth usage and access was a major public policy driver in establishing the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act") in the first place.

Because premium cigars are smoked infrequently and are not used by minors, they are distinct from all other tobacco products and thus don't rise to the level warranting FDA regulatory oversight.

Congress enacted the Tobacco Control Act "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[1] FDA's own research, however, has found that one of the most critical of Congress's stated reasons for regulating tobacco products – youth use and addiction – are not present in premium cigars.

First, the Population Assessment of Tobacco and Health ("PATH") study, administered by the FDA and the National Institutes of Health, has founded that children do not smoke premium cigars. Last year, FDA staff published an analysis of PATH data in the *New England Journal of Medicine* and reported that there is **no statistically significant use of "traditional cigars"[2] by persons younger than 18 on a "daily" or "frequent" basis.**[3] Instead, in an article in *Nicotine and Tobacco Research*, FDA staff explained that the median age of "first regular use" for "premium cigars" is 24.5 years old with a 95% confidence interval of 18.8 years old to 32.6 years old.[4] Accordingly, FDA's own staff and research have found that minors are not using premium cigars.

Second, the National Adult Tobacco Survey ("NATS"), administered by the U.S. Centers for Disease Control and Prevention ("CDC"), found that premium cigars are used infrequently. An article written by FDA staff and published in the CDC's *Morbidity and Mortality Weekly Report* analyzed 2012–2013 NATS data and found that **96.7 percent of premium cigar consumers smoke fewer than one premium cigar per day**.[5] The aforementioned article in *Nicotine & Tobacco Research* on PATH data concluded that the median premium cigar consumer smokes 1.7 cigars per month.[6] Because the typical consumer smokes fewer than two premium cigars per month, the patterns of use for premium cigars are simply not consistent with addiction.

The fact that premium cigars are smoked infrequently is particularly important because government-funded studies of data spanning decades have concluded that smoking cigars infrequently presents no statistically significant increase in the rate of mortality over non-smokers as the difference is within the study's margin of error. Earlier this year, FDA staff and other researchers published an article in the Journal of American Medical Association (*"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 less than one cigar per day – just as 97

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[1] 21 U.S.C. 387 note § 3(2).
[2] 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 is historic Tampa cigar factory.
[3] 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).
[4] Corey, C., NICOTINE & TOBACCO RESEARCH, at 5.
[5] 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).
[6] Corey, C., NICOTINE & TOBACCO RESEARCH, at 7. This study also concluded that 93.3% of premium cigar consumers smoked less than one cigar per day, slightly lower than the 96.7% reported in 2014.

percent of premium cigar smokers do.[7] This research confirmed the analysis published in 1998 by the National Cancer Institute in Monograph No. 9.[8] The issues of youth access, patterns of use, and health effects of premium cigars are discussed in much greater depth in the comments submitted on behalf of the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America in response to the ANPRM on premium cigars last summer.[9]

The Economic Loss as a Result of Over-Regulation Would Be Considerable

It is important for FDA to remember that premium cigars are just 0.5 percent of the tobacco industry and are comprised of many small, family-owned businesses. Because premium cigars are made without modern technology, startup costs in our industry are extremely low. Accordingly, our industry is filled with many small manufacturers. Unlike other parts of the tobacco industry that have massive market shares and in-house scientists, regulatory exports, and laboratories, premium cigar manufacturers lack these internal resources. Therefore, preparing substantial equivalency reports will take much longer and be more difficult for premium cigar manufacturers than other larger tobacco manufacturers.

CRA recently commissioned an economic impact study on the implications of the FDA deeming regulation over premium hand rolled cigars performed by David Zorn, Ph.D., (a consultant with Mangum Economics and an adjunct professor at Antonin Scalia Law School. Previously, he was an economist with the U.S. Food & Drug Administration). According to Dr. Zorn, "Using FDA's own cost estimates, the regulations will likely cause 85 to 90 percent of domestic cigar manufacturers and importers (320-338 small businesses) to go out of business, leading to the loss of over 3,500 U.S. manufacturing jobs and almost 1,800 jobs at U.S. importers."

Dr. Zorn continued, "Because handmade cigars have the highest cost of compliance per cigar, almost all of the cigar manufacturers and importers that go out of business because of this rule will be manufacturers and importers of premium handmade cigars. The expected reduction in the number of handmade cigars on the market due to the rule is also likely to cause the closure of approximately 500 tobacco retailers and the loss of as many as 19,800 U.S. retail jobs."

Rocky Patel Cigars estimates that Harmful and Potentially Harmful Constituent Testing could exceed $64 million dollars. That is in addition to annual legal fees that would cost $500,000.00 per year as well as User Fees that currently cost $1,500,000.00 per year.

Gradual Monopolization of the Tobacco Market

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[7] 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).
[8] "Cigars Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9," NATIONAL CANCER INSTITUTE (1998) at *i*.
[9] Comments from the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America (Jul. 25, 2018), https://www.regulations.gov/document?D=FDA-2017-N-6107-8583.

If FDA includes premium cigars in its final regulation, it is likely to lead to the perverse consequence of driving the vast majority of small-business premium manufacturers out of the marketplace and consolidating the industry in the hands of the largest "Big Tobacco" companies.

Well-established economic theory demonstrates that raising costs in a given sector tends to drive the market toward monopolization. As costs rise, smaller manufacturers are driven from the market. Larger manufacturers are able to take advantage of economies of scale and find it easier to absorb costs. In the tobacco market, this has played out exactly as theory predicts. In the wake of the 1998 Master Settlement Agreement, the cigarette market in the United States has continued to consolidate and is now overwhelmingly dominated by the Big Three manufacturers.[10] The trend that has played out in the cigarette market is almost certain to repeat itself if FDA includes premium cigars in its final rule.

The most likely result of subjecting premium cigars to this FDA regulation is nearly total market consolidation of the premium space into the hands of these large tobacco companies. Nearly all premium manufacturers are small businesses and will simply not be able to bear the estimated costs of the rule. FDA's itself estimates that as much as 50% reduction in the premium cigars marketplace due to the costs of the rule, and that estimate is based on a cost figure that incorrectly fails to take into account one of the most expensive proposed provisions.

FDA Failed to Estimate One of the Rule's Most Significant Costs

HPHC Testing

Executive Order 12866 requires FDA to assess all costs and benefits of its rulemaking, to the extent that it is feasible to do so, prior to issuance of a final rule.[11] The goal of E.O. 12866 is twofold. First, disclosure of costs and benefits provides transparency to the public, including the affected industry and other interested parties. Second, an assessment of costs and benefits is intended to inform the regulatory process and to help FDA adopt policies that "impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and government entities), consistent with obtaining the regulatory objectives." FDA's proposed Deeming rule failed to assess some of the most critical costs and benefits to the regulated industry. The proposed rule thus lacks that transparency and accountability required by E.O. 12866.

If finalized, FDA's proposed rule would require all deemed products entering commerce after February 15, 2007 to receive premarket approval. All products introduced after this "grandfather date" would either need to demonstrate their "substantial equivalence" to

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[10] For more information on tobacco cartelization in the wake of the MSA, see Viscusi, W. Kip, *Smoke-Filled Rooms: A Post-Mortem of the Tobacco Deal*, 2002.

[11] E.O. 12866, available at: http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf

an existing product or submit a detailed application demonstrating that their marketing is appropriate for the protection of public health. The latter pathway is expected to involve much more detailed and burdensome submissions, and FDA's proposed rule makes clear that the Agency expects nearly all cigar manufacturers will pursue a determination of substantial equivalence for their products. Obtaining a determination of substantial equivalence requires manufacturers to submit descriptions of their products (and the comparison predicates), as well as scientific information on their "harmful and potentially harmful constituents."

The HPHC reporting required of each post-grandfather product will be a major cost-driver of the rule and will be particularly burdensome on manufacturers of premium cigars. Premium cigar makers generally do not have in-house laboratories and will thus need to contract with independent labs to perform that testing. FDA chose not to estimate any of these costs in the preliminary RIA:

Although this provision would create an obligation that imposes costs, the Secretary is also required to promulgate regulations concerning the testing and reporting of constituents. We will estimate the cost of compliance with testing and reporting when those regulations are promulgated...[12]

This failure to include the costs is unjustified, as FDA has already published guidance outlining its policy on HPHCs. In 2012, the Agency issued a document outlining 93 constituents that it believes are harmful or potential harmful in tobacco products. Because of the extensive nature of that list, FDA further explained that it is currently requiring testing only on a subset of 20 of those HPHCs. Thus, the policy regarding HPHCs is already well established for items already under FDA's authority. While FDA is expected to determine new HPHCs for newly deemed products, there is no reason to believe that the list will be substantially different for cigars as opposed to cigarettes. Certainly the established HPHC list at least provides sufficient precedent for FDA to use as a baseline economic estimate. Including these calculations as a baseline estimate is much more transparent and within the spirit and letter of E.O. 12866 than simply providing no estimate of a major cost-driver at all. Even if FDA did intend to adopt a narrower HPHC list for cigars, that subsequent rulemaking could revise the economic information; but there is no good reason that the costs of this testing should not be accounted for in the rulemaking at hand. In fact, doing so is clearly required by E.O. 12866.

The FDA Should Exempt Premium Cigars From FDA regulation, Including PMTA/Substantial Equivalency Testing

Subjecting premium cigars to the same rigorous and costly substantial equivalency process developed for cigarettes and mass-market tobacco products is not necessary for the FDA to achieve its goals – particularly since FDA's research has found that children are not using premium cigars, premium cigars are smoked infrequently and when smoked infrequently, there is no statistically significant increase in mortality

[12] Deeming Rule Preliminary Regulatory Analysis (RIA), 79 FR 23141 (April 24, 2014) at 33.

outside the assigned margin or error. Premium cigars are distinct, handcrafted products made by small family businesses that lack the expertise and capacity of large tobacco companies to prepare these reports. Processing all of the substantial equivalency reports for premium cigars will take a grossly disproportionate amount of limited agency resources, diverting it from the agency's other regulatory priorities. Therefore, FDA should exempt premium cigars from FDA regulation, including the substantial equivalency process. Dr. Zorn noted, "FDA could achieve the same level of public health protection by not regulating handmade cigars in the same way that it regulates cigarettes. At the same time, the agency could allocate the $198 million of cost savings to apply against other FDA regulations that could actually improve public health." The regulatory framework, however, continues to create uncertainty in the marketplace and we would hope that at the very least, the FDA agrees to smaller warning labels, no constituent testing and having the broadest standard possible to define substantial equivalent products given the unique nature of premium cigars and the variability due to agricultural hand-processes. A broad substantial equivalence standard would simply define equivalents as dark, air-cured tobaccos with vegetable glue.

Economic Impacts on Domestically Owned Premium Cigar Companies with Production Overseas Could have Serious Immigration and Security Implications

Under EO's 12866 and 13563, FDA is required to take into account, and to include in its economic analysis of the proposed Deeming rule, any trade and international economic impacts that may result from the provisions. FDA has not done this, and the Agency ignores substantial costs for foreign growers and potentially extremely large job losses in foreign countries.

95 percent of handmade cigars are manufactured in foreign countries, primarily in Latin America but also in some African nations. In Honduras, Nicaragua and the Dominican Republic alone, handmade cigars account for over 350,000 estimated jobs in the agricultural, craftsman, production, support services and distribution sectors. Cigars create jobs in Cameroon and the Central African Republic – about 3,000 jobs in each country. Also likely to be seriously affected are Ecuador, Brazil, Columbia, Puerto Rico, Costa Rica, Peru, Panama, Indonesia, Mexico, and Cuba. All these countries are certain to be seriously impacted by FDA's rule. While it is difficult to assign precise job-loss figures, FDA's own analysis claims that as many as 50 percent of cigar brands will be eliminated from commerce, a figure that CRA believes (and elsewhere demonstrates) is a lower bound estimate. Those figures imply huge losses of revenue in all affected countries and potentially the loss of hundreds of thousands of jobs in their agricultural sectors. The unintended consequences of these job losses could create immigration and security implications in the United States of America.

The governments of these countries have on several occasions communicated their concerns to their counterparts in the State Department and National Security Council and the former Dominican Ambassador to the United States testified before the House Foreign Affairs Committee's Subcommittee on Western Hemisphere that the proposed

regulations would have a dramatic impact on that nation's people. Nevertheless, FDA has failed to take into account these very real concerns.

If FDA intends to finalize its proposed Deeming regulation, it must include analysis of the impacts on these countries in its Final Regulatory Impact Analysis, and it should use that information to conclude that premium cigars should not be included in the rule.

Closing

We firmly maintain that were a population risk evidentiary standard applied, economic impact and cost benefit analysis accurately performed, and the science considered in an appropriate manner, the agency would fully realize the rationale for premium cigar exclusion from the regulatory framework. While it might be beneficial for FDA to regulate many cigar products, it cannot possibly be justified for premium cigars, a category for which there are nearly no demonstrated benefits and extremely high costs. FDA recognized this in the proposed rule by including Option 2, an exemption for the premium category, but had concerns that any definition might be over-inclusive and allow for regulatory arbitrage. Those fears should be allayed: with a minor change, FDA's definition for premiums can successfully exempt the products that need to be exempted while preventing free riders. FDA's definition focuses on intrinsically costly measures of cigar quality. By their very nature, it is not possible for mass-market cigars to mimic these qualities.

FDA's proposed deeming of premium cigars has few or no benefits, huge costs, and serious unintended consequences. The FDA should select exemption for premium hand rolled cigars. We appreciate the attention and advocacy that the Senate Small Business Committee has demonstrated with regards to noting the adverse economic impacts of the FDA deeming regulation over premium, hand-rolled cigars.

Sincerely,

Rocky Patel,
Rocky Patel Premium Cigars

October 30, 2018

The Public Health, Financial and Employment Impacts of Excluding Handmade Cigars from Coverage by FDA's Final Rule

ECONOMIC INFORMATION FOR FDA'S CENTER FOR TOBACCO PRODUCTS IMPLEMENTATION OF EXECUTIVE ORDERS 13771 AND 13777

MANGUM economics

4201 DOMINION BOULEVARD, SUITE 114
GLEN ALLEN, VIRGINIA 23060
804-346-8446
MANGUMECONOMICS.COM

About Mangum Economic Consulting, LLC

Mangum Economic Consulting, LLC is a Richmond, Virginia based firm that specializes in producing objective economic, quantitative, and qualitative analysis in support of strategic decision making. Examples of typical studies include:

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Introduction

The U.S. Food and Drug Administration (FDA) has requested comments and information to help it identify regulations that can be modified, repealed, or replaced to achieve meaningful reduction of regulatory burdens while achieving FDA's public health mission and fulfilling its statutory obligations. The agency's Regulatory Reform Task Force must attempt to identify regulations that, among other things:

- eliminate jobs, or inhibit job creation or
- impose costs that exceed benefits.

This report shows that the FDA's Final Rule deeming handmade cigars subject to Chapter IX of the Food, Drug, and Cosmetic Act is a regulation that is certain to eliminate jobs and impose substantial costs that exceed any benefits of the rule.[1]

The agency also asked that comments address several questions. This report addresses two such questions:

1. Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.
2. Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

The answer to each of these questions is "yes." As detailed in the rest of this report:

1. Yes, compliance with the regulation will be so difficult and costly that it threatens to put almost all U.S. handmade cigar manufacturers and importers out of business. *Using FDA's own cost estimates*, the regulation likely will cause 85 to 90 percent of domestic cigar manufacturers and importers (320-338 small businesses) to go out of business, leading to the loss of over 3,500 U.S. manufacturing jobs and almost 1,800 jobs at U.S. importers. Because handmade cigars have the highest cost of compliance per cigar, almost all of the cigar manufacturers and importers that go out of business because of this rule will be manufacturers and importers of handmade cigars. The expected reduction in the number of handmade cigars on the market due to the rule is also likely to cause the closure of at least 494 tobacco retailers and the loss of as many as 19,800 U.S. retail jobs.
2. Yes, FDA could achieve the goal of the regulation ("to reduce death and disease from tobacco products"[2]) and the same level of public health protection by excluding handmade cigars from

[1] Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) ("Final Rule").
[2] 81 Fed. Reg. 28975 (May 10, 2016).

the Final Rule and allocate the $198 million (discounted at 3%) of regulatory cost savings to apply against other FDA regulations that could improve public health.

Discussion of FDA's Estimates of Costs for Handmade Cigar Manufacturers and Importers and Updates to FDA's Estimates

For this report on the business and job consequences of FDA's Final Rule for the cigar industry, we will use FDA's estimates of costs for the rule. Tables 1 and 2 show FDA's estimates for the number and size of U.S. cigar manufacturers and importers covered by the Final Rule. The tables also show more recent data obtained for this report to update FDA's cost estimates.

Table 1. Number and Characteristics of U.S. Cigar Manufacturers

	FDA	This Report
Domestic Cigar Manufacturing Establishments	113[3]	160[4]
Percentage of Domestic Tobacco Manufacturing Establishments per Employee Size Category	0-4 employees: 37%[5] 5-9 employees: 9% 10-19 employees: 5% 20-99 employees: 29% 100-499 employees: 10% 500+ employees: 11%	1-4 employees: 44%[6] 5-9 employees: 9% 10-19 employees: 8% 20-99 employees: 21% 100-499 employees: 15% 500-999 employees: 2% 1,000+ employees: 2%
Portion of Tobacco Manufacturers that Meet SBA's Definition of Small	89%[7]	98+%[8]

[3] FDA, Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis ("FRIA"), Table 4. Available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf
[4] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.
[5] FRIA, Table 41.
[6] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.
[7] FRIA, Table 40.
[8] Percent of establishments with fewer than 1,500 employees based on U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.

Table 2. Number and Characteristics of U.S. Cigar Importers

	FDA	This Report
Domestic Cigar Importing Establishments[9]	216	216
Percentage of Domestic Tobacco Importing Firms per Employee Size Category	0-4 employees: 45%[10] 5-9 employees: 18% 10-19 employees: 13% 20-99 employees: 15% 100-499 employees: 6% 500+ employees: 2%	1-4 employees: 47%[11] 5-9 employees: 15% 10-19 employees: 13% 20-99 employees: 17% 100-249 employees: 5% 250+ employees: 3%
Portion of Tobacco Importers that Meet SBA's Definition of Small	92%[12]	97%[13]

FDA estimated that there are 113 domestic cigar manufacturers and 216 cigar importers based on 2013 data from the Alcohol and Tobacco Tax and Trade Bureau. Data from the 2015 U.S. Census Bureau, County Business Patterns indicate that there are 160 domestic cigar manufacturers, an increase of 42 percent in two years. The Census data on tobacco importers is not granular enough to provide a more up to date estimate of the number of cigar importers. We therefore use FDA's estimate in this report, so that the total number of domestic cigar manufacturers and importers is 376 (an increase of 14 percent over the estimate that FDA made using 2013 data). However, if the number of cigar importers has increased since 2013 at a rate similar to that of domestic cigar manufacturers, then the impact of the rule on the cigar import sector (i.e., the sector relevant to handmade cigars) is underestimated here.

The U.S. Small Business Administration (SBA) defines a "small" tobacco manufacturer as one that has fewer than 1,500 employees and a "small" tobacco importer as one that has fewer than 250 employees.[14] FDA used 2007 Census data to estimate the percentages of cigar manufacturers (89%) and cigar importers (92%) that meet SBA's definition of a small tobacco manufacturer or importer. However, the 2007 Economic Census aggregated into one category all firms with 500 or more employees. This led FDA to underestimate the number of tobacco manufacturers and importers that SBA would classify as "small." The 2015 Census data is more disaggregated and separates firms with 500 to 999 employees from those with 1,000 or more employees. Using the 2015 U.S. Census Bureau County Business Patterns data, we can say that 98 percent or more tobacco manufacturers meet SBA's definition of a small business (1,500 tobacco manufacturing employees) because 98 percent of tobacco manufacturing firms

[9] FRIA, Table 4.
[10] FRIA, Table 41.
[11] U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[12] FRIA, Table 40.
[13] Percent of establishments with fewer than 250 employees based on U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[14] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, 2016, p 8.

have fewer than 1,000 employees. Using the more up to date data also shows that 97 percent of tobacco importers have fewer than 250 employees.

Table 3 shows the cost of making handmade cigars subject to FDA regulation. FDA's Final Regulatory Impact Analysis reports the present value of the costs for cigar manufacturers and importers. However, it does not specifically report the present value of costs for handmade cigar manufacturers and importers. FDA's Preliminary Regulatory Impact Analysis, however, shows that handmade cigar manufacturers and importers account for 86 percent of the cost for all cigar manufacturers and importers.[15] Adjusting the present value of the costs for handmade cigar manufacturers and importers to account for the higher number of current domestic cigar manufacturers increases the costs by 14 percent to $197.8 million (discounted at 3%) or $156.9 million (discounted at 7%). If FDA exempts handmade cigars from the Final Rule, that is the amount that FDA could apply under Executive Order 13771 toward other rulemakings that could promote and protect public health.

Table 3. Cost of Covering Handmade Cigars

	FDA	This Report
Present Value of Costs for Cigar Manufacturers and Importers[16]	Discounted @ 3%: $201,800,000 Discounted @ 7%: $160,000,000	
Handmade Cigar Portion of Total Cigar Costs[17]	86%	
Present Value of Costs for Handmade Cigar Manufacturers and Importers	Discounted @ 3%: $173,500,000[18] Discounted @ 7%: $137,600,000	Discounted @ 3%: $197,800,000[19] Discounted @ 7%: $156,900,000

Handmade Cigar Manufacturers and Importers Forced to Close

The Final Rule imposes very large costs on cigar manufacturers and importers. In response to a comment by one cigar trade association, FDA states, "we acknowledge in our analyses of the proposed and final rules that small entities may be adversely affected, and many may exit."[20] However, FDA never attempts to estimate the number of cigar manufacturers or importers that will be forced to shut down as a result of the rule.[21] The data to make reasonable estimates of cigar industry closure exist, and we use them in this report to reveal the business implications of the rule.

[15] FDA, Preliminary Regulatory Impact Analysis ("PRIA"), Table 35.
[16] FRIA, Table 32.
[17] PRIA, Table 35, ($115.6 + $224.2) ÷ ($115.6 + $224.2 + $53.8) = 0.86.
[18] 86% of $201.8 million and $160 million.
[19] 142% of $173.5 million and $137.6 million to adjust for the additional manufacturers.
[20] FRIA, p 47.
[21] In response to comments on the effect of the rule on business closure and products removed from the market, FDA refers to a section of the FRIA with the heading, "Costs of Market Adjustments." The section merely contains vague language about potential effects of the rule on business operations and products offered. FDA offers no attempt at quantification of the effects of the rule on business closure, jobs lost, or products withdrawn from the market. FDA does not even offer qualitative, relative indications of the size of the effects (e.g., small, large, significant, etc.). See FRIA, p 104.

To put the costs that FDA estimated for cigar manufacturers and importers into a context relevant for business, we obtained data on annual sales revenues for domestic cigar manufacturers and tobacco industry net profit margins. We do not have data on cigar manufacturing or importing net profit margin. As a proxy, we use CSIMarket data on net profit margins for publicly-traded tobacco product manufacturers. In the third quarter of 2017, the 14 publicly-traded tobacco product manufacturers reported a net profit margin of 22 percent on an annual basis. Applying this net profit margin to November 2017 data from Dun & Bradstreet on annual sales revenue for certain U.S. cigar manufacturers strongly suggests that FDA's estimates of the costs of the rule for cigar manufacturers and importers will exceed the total profit of the vast majority of domestic cigar manufacturers and importers.

Table 4 shows FDA's cost estimates and the data used to put the cost of the rule in context.

Table 4. Impact of the Rule on Cigar Industry Profitability

	FDA	This Report
Cost per Small Cigar Manufacturer or Importer[22]	Year 1: $277,750 - $397,350 Year 2: $291,760 - $411,290 Year 3+: $235,060 - $256,960	
Annual Revenue for Cigar Manufacturers[23]		Minimum: $48,720 Median: $252,580 Maximum: $64,780,440
Net Profit Margin for Publicly-Traded Tobacco Companies[24]		22%
Annual Net Profit for Cigar Manufacturers[25]		Minimum: $10,720 Median: $55,570 Maximum: $14,251,700
Percent of Cigar Manufacturers or Importers for whom FDA Compliance Cost Estimates Exceed Net Profits[26]		Years 1 & 2: 87% - 89% Year 3+: 85%

FDA estimates that the year 1 cost of compliance for a small cigar manufacturer or importer will range between $277,750 and $397,350. Costs in year 2 increase to between $291,760 and $411,290. Then in the third and following years costs decrease and remain stable at a range of $235,060 and $256,960. Assuming that FDA's estimates are accurate, then the Dun & Bradstreet and CSIMarket data indicate that half of the cigar manufacturers in the U.S. have annual profits that are one-fifth of the lowest-

[22] FRIA, Table 42.
[23] Dun & Bradstreet, SIC Code 21210000 (specific for cigars).
[24] CSIMarket.com data for the tobacco industry reported for Q3 2017 and the trailing 12 months. https://csimarket.com/Industry/industry_Profitability_Ratios.php?ind=508
[25] Annual revenue amounts multiplied by 22% net profit margin factor.
[26] Calculated using data from Dun & Bradstreet, SIC Code 21210000 (specific for cigars).

bound cost of compliance with the rule. In fact, the lowest-bound cost of compliance with the rule exceeds the total sales revenue of half of the domestic cigar manufacturers.

Applying the net profit margin factor to the annual sales revenue data for each of the businesses in the Dun & Bradstreet database indicates that FDA's first and second year compliance cost estimates exceed the total profit of 87 to 89 percent of U.S. cigar manufacturers. And even if the businesses find some way to fund the initial start-up costs of the rule, the ongoing annual costs of the rule will exceed the annual profits of 85 percent of U.S. cigar manufacturers. The costs of the rule will make 85 to 90 percent of domestic cigar manufacturers unprofitable. Under these circumstances, it is almost certain that the rule will force 88 percent of U.S. cigar manufacturers out of business.

It is also important to consider that handmade cigar manufacturers are the smallest of U.S. cigar manufacturers with lower annual revenues and profits than U.S. machine-made cigar manufacturers. Therefore, it is very likely that the 85 percent of cigar manufacturers that the rule will cause to close are handmade cigar manufacturers.

FDA estimates that the costs of the rule for cigar manufacturers and importers are the same. 27 Dun & Bradstreet does not have data granular enough to estimate cigar importer annual revenues. CSIMarket data for the wholesale industry (of which cigar importers are a part) indicate that net profit margins are extremely low – about 2 percent for the year ending in the third quarter of 2017. The very low profit margins mean that even small increases in costs pose serious threats to the viability of the business if cost increases are not passed on as FDA asserts. Even without more information, we believe that it is very reasonable to use the impact of the rule on cigar manufacturer profitability as a proxy for the impact of the rule on cigar importer profitability. Therefore, we estimate the rule to make 88 percent of cigar importers so unprofitable that they cease operation.

Jobs Lost in U.S. Cigar Manufacturing and Importing

The closure of U.S. cigar manufacturers and importers will put thousands of employees out of work. Tables 5 and 6 show the breakdown of the percentage of cigar manufacturing or importing facilities and cigar manufacturing or importing employees by the employee-size category of the establishment. If we assume that the establishments with the fewest employees are those that will be forced out of business by the rule, then we can estimate the number of U.S. manufacturing and importing jobs that will be lost because of the rule.

Eighty-two percent of U.S. cigar manufacturers have fewer than 100 employees. We estimate that all 2,071 employees at those manufacturing establishments will lose their jobs as a result of the rule. The 2015 Census Bureau County Business Patterns reports 17 manufacturing establishments with 100 to 249 employees. As a group, those 17 establishments employ 2,543 people, or 150 people per establishment.

[27] FRIA, Table 42.

Adding the employee equivalent of 9.6 additional establishments (1,440 employees) to the 2,071 employees in establishments with fewer than 100 employees brings the total manufacturing jobs lost equivalent to 88 percent of manufacturing establishments that have profits that are less than the start-up costs of the rule. Therefore, we estimate that the rule causes the loss of 3,511 U.S. manufacturing jobs.

Table 5. 2015 U.S. Census Data on the Size Distribution on Manufacturers and Employees

	Percentage of Manufacturers (out of 160 total U.S. cigar manufacturing establishments)	Number of Employees (out of 13,872 total U.S. cigar manufacturing employees)
Percentage of Domestic Tobacco Manufacturing Establishments and Employees per Employee Size Category[28]	1-4 employees: 44% 5-9 employees: 9% 10-19 employees: 8% 20-99 employees: 21% 100-249 employees: 11% 250-499 employees: 4% 500-999 employees: 2% 1,000+ employees: 2%	1-4 employees: 93 5-9 employees: 97 10-19 employees: 159 20-99 employees: 1,722 100-249 employees: 2,543 250-499 employees: 2,466 500-999 employees: 2,260 1,000+ employees: 4,532

86 percent of cigar importers have fewer than 50 employees. We estimate that all 1,450 employees at those importing establishments will lose their jobs as a result of the rule. To go from 86 percent of the 216 cigar importing establishments to 88 percent (the percent of importers with FDA-estimated costs of the rule exceeding profits), we need to add 2 percentage points from the 50-99 employee size category. Since 6 percent of the total number of cigar importers are in that category, that additional portion needed is one-third of the employees from that size category – 332 employees. So adding 332 employees to the 1,450 employees in establishments with fewer than 50 employees brings the total importing jobs lost equivalent to 88 percent of importing establishments that have profits that are less than the start-up costs of the rule. Therefore, we estimate that the rule causes the loss of 1,782 U.S. importing jobs.

[28] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.

Table 6. 2015 U.S. Census Data on the Size Distribution on Importers and Employees

	Percentage of Importers (for 216 U.S. cigar importing establishments out of 1,485 total tobacco importing establishments)	Number of Employees (for 7,382 U.S. cigar importers out of 50,753 total tobacco importing employees)
Percentage of Tobacco Importing Establishments and Employees per Employee Size Category[29]	1-4 employees: 47% 5-9 employees: 15% 10-19 employees: 13% 20-49 employees: 11% 50-99 employees: 6% 100-249 employees: 5% 250+ employees: 3%	1-4 employees: 161 5-9 employees: 213 10-19 employees: 363 20-49 employees: 713 50-99 employees: 997 100-249 employees: 1,628 250+ employees: 3,307

Therefore, the FDA-estimated costs of the Final Rule imply that 88 percent of U.S. cigar manufacturers and importers (331 establishments) will become unprofitable because of the rule and have to close, resulting in the loss of 5,300 U.S. jobs.

Closure of Tobacco Retailers

The rule imposes onerous costs on cigar manufacturers and importers. By FDA's own estimates, at a minimum, each small cigar manufacturer and importer will have to pay over one-quarter of a million dollars a year to comply with the rule. And according to FDA, even costs in the out years could still be that high on an annual basis.[30]

Built into FDA's cost estimates in its Preliminary Regulatory Impact Analysis was the expectation that 10 percent to 50 percent of cigar UPCs (also referred to as SKUs or product/package combinations) would no longer be offered for sale because the costs of the rule would make producing them unprofitable.[31] In its Final Regulatory Impact Analysis, FDA changed its estimate of the percentage of cigar products that would no longer be offered as a result of the rule to 5 percent, without offering any justification or explanation for such a dramatic change.[32]

Nevertheless, we can use FDA's estimates of product reduction to estimate the effect of the rule on tobacco retailers, almost all of which sell handmade cigars. According to the U.S. Census Bureau County Business Patterns, in 2015 there were 11,140 tobacco retailers in the U.S., including many of which

[29] U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[30] FRIA, Table 42.
[31] PRIA, pp. 26, 29, and 60.
[32] FRIA, p 47.

specialize in selling handmade cigars.[33] In order to stay in business, specialty cigar stores depend on being able to offer a very large selection of handmade cigars, a selection of new product additions, a special selection of rare handmade cigars (or even boutique cigars that are unique to a single store), and store personnel with extensive knowledge and experience with handmade cigars in order to assist customers in selecting new brands, product lines, varieties and sizes. Handmade cigar smokers ("cigar aficionados" as they are often referred to) are similar to wine and distilled spirits connoisseurs, craft brew drinkers, people who fish with flies, or "foodies." Consumption of the product is part avocation. Searching for, learning about, and trying new and unique items is part of the attraction of the purchase. Specialty cigar retailers are highly dependent on a wide offering of products. The fewer products and the fewer new products there are available for customers, the less valuable are knowledgeable and experienced sales staff. And the fewer products available for purchase in the category, the fewer tobacco retailers the market will support.

The 2015 County Business Patterns reports a total of 11,140 tobacco stores in the U.S. employing a total of 42,106 people, or about 4 employees per store on average. We assume that a reduction in product variety causes a proportional decrease in the number of stores.

Table 7 shows the number of tobacco stores estimated to close using this method.

Table 7. Estimates of Tobacco Retail Store Closure and Jobs Lost

	5% Fewer SKUs	10% Fewer SKUs	50% Fewer SKUs
Tobacco Stores Closed	494	989	4,944
Tobacco Store Jobs Lost	1,976	3,956	19,776

We provide estimates for all three of the percentages of product reduction that FDA has used during the rulemaking. We include the higher estimates from the Preliminary Regulatory Impact Analysis because FDA offered no rational basis for the dramatic reduction that it adopted in the Final Regulatory Impact Analysis. Moreover, considering that almost 90 percent of U.S. cigar manufacturers and importers will be forced to close because the rule will make it unprofitable for them to operate, the higher estimates of SKUs lost because of the rulemaking seem to be the most reasonable.

Financial Stress on Small, Family Farms

FDA's Final Regulatory Impact Analysis gives a brief mention to the effect of implementation of the Final Rule on tobacco farms in the United States. FDA refers to data from the U.S. Department of Agriculture that one percent of tobacco production was for use in cigars. The agency then states that once the Final Rule goes into effect tobacco farmers may switch to farming other crops. FDA fails to acknowledge that farms that grow tobacco, and especially cigar tobacco, will have difficulty switching to other crops

[33] U.S. Census Bureau, County Business Patterns, 2015, NAICS 453991.

without a loss of income. Tobacco for cigars is a high value crop, and it is usually difficult for farmers to switch to other high value crops. The farms that grow tobacco for handmade cigars are small, family farms like the Jepson Family Farm Partnership growing in Simpson County, Kentucky and Robertson County, Tennessee.[34] Jepson Farms quit growing burley tobacco used in cigarettes several years ago to grow 150 acres of dark tobacco used in cigars.[35] Growing tobacco for cigars has been instrumental in keeping the Daughter's & Ryan farm in St. James Parrish, Louisiana operating.[36] In Lake County, Florida, a small, start-up, Florida Sun Grown Farm grows premium tobacco exclusively for cigars.[37] In Lancaster County, Pennsylvania, almost 1,000 Amish family farms grow tobacco, some of it as wrappers for cigars.[38] The income from tobacco is important to keeping the farms in business.[39] In the Connecticut River Valley, many small, family tobacco farms have been under significant financial pressure for years. The key to staying in business, they say, is growing shade tobacco that is used for premium cigar wrappers.[40] Farmers in Connecticut rotate the crops of shade tobacco with high-end broadleaf tobacco, both of which are used in handmade cigars.[41] So small, family farms that supply tobacco for handmade cigars from Florida to New England will be negatively impacted by the Final Rule. FDA failed to respond in any meaningful way to the concerns about the impacts on tobacco growers raised in comments, even though comments were offered on the effect of the rule on agriculture.[42] Moreover, although there are hundreds of small tobacco farms, and the Final Rule will certainly impose a significant economic impact on a substantial number of small entities (as addressed by the Regulatory Flexibility Act), FDA did not even make mention of small tobacco farms on its Small Entity Analysis as required by the Regulatory Flexibility Act.[43]

Additional Costs and Negative Impacts of the Rule

The estimates of business closures and jobs lost in this report are based on FDA's own estimates of the cost of compliance with the Final Rule. In numerous comments and submissions to FDA, the handmade cigar industry has disputed FDA's cost estimates and provided FDA with justification for higher cost estimates. If FDA accepts those higher cost estimates and eliminates handmade cigars from the Final

[34] http://www.jepsonfamilyfarms.com/about-us/
[35] Rosalind Essig, "How Tennessee Tobacco Growers Transition Through Change," FarmFlavor.com, March 19, 2018. Available at https://www.farmflavor.com/tennessee/how-tobacco-growers-transition-through-change/
[36] "Perique: A Resurrection Story," Tobacco Business, January 17, 2018. Available at http://tobaccobusiness.com/perique-resurrection-story/
[37] Nicolás Antonio Jiménez, "At the Source of Florida Sun Grown Tobacco," Cigar Snob Magazine, June 1, 2016. Available at http://www.cigarsnobmag.com/news/florida-sun-grown-cigar-tobacco
[38] Lenay Ruhl, "Lancaster County Leads Pennsylvania's Tobacco Business," Central Penn Business Journal, September 25, 2015. Available at http://www.cpbj.com/article/20150925/CPBJ01/309239998/lancaster-county-leads-pennsylvanias-tobacco-business
[39] Tom Lowry, "Tobacco In Amish Country," Cigar Aficionado, March/April 1997. Available at https://www.cigaraficionado.com/article/tobacco-in-amish-country-7556
[40] Gregory B. Hladky, "Foreign Competition, Labor Costs Push Connecticut Shade Tobacco Farmers to the Edge," Hartford Courant, June 15, 2017.
[41] Andrew Nagy, "Broadleaf of Bust," Cigar Aficionado, September 9, 2016. Available at https://www.cigaraficionado.com/article/broadleaf-or-bust-19005
[42] FRIA, p 49.
[43] FRIA, pp 128-134.

Rule, then FDA may count those additional regulatory cost savings (in addition to the costs for handmade cigars that it estimated in the Final Rule) toward the costs for other new rules that could protect public health.

An example of serious underestimates in FDA's cost estimates relate to the cost of adding new warning labels to cigar packaging. FDA presents its analysis of the cost of the Final Rule in its FRIA. A significant part of the analysis is FDA's estimate of the cost of adding warning labels to cigar packages using its Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration.[44]

The labeling cost model is designed to estimate three components of a labeling change: label design costs, inventory costs, and testing costs. However, FDA's analysis counts only label design costs because it assumes away the other two cost components. FDA assumes that manufacturers of products affected by the rule will not test the acceptability of the redesigned labels with consumers because the addition of the warnings is required by FDA. FDA also assumes that all products covered by the Final Rule are branded because FDA does not have a way to identify private label products.[45] That assumption prevents the model from estimating any inventory costs for the label changes, because built into the model is the assumption that branded products do not maintain label inventories in excess of 24 months.

According to the model, label design costs include administrative labor, graphic design labor, prepress labor, recordkeeping, prepress materials, and printing plates.[46] These costs are determined by the type of packaging and printing associated with the product to be relabeled. It costs more to change labels on products with more expensive packaging materials or more colorful printing. Therefore, in order for the labeling model to yield cost estimates that are reasonable approximations of the actual costs, the packages and labels used in the model must be reasonably related to the packages and labels being estimated.

The final report for the model explains that the cost to change all tobacco product packages (including premium cigar boxes) is based only on the cost to change cigarette packages. The final report states, "In the labeling cost model, product subcategories were assigned with package-label types according to the package-label type used by the top-selling product in that subcategory [....] Thus, we assigned the most common package-label type for each product subcategory based on the top-selling products in each product subcategory in 2008."[47] All tobacco products are in one subcategory.[48] Because cigarettes are the top-selling product in the tobacco subcategory, FDA analyzes all tobacco products as requiring

[44] FRIA, page 106.
[45] FRIA footnote 65.
[46] RTI International, Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Chapter 3 ("Labeling Cost Model Report"). Available at https://www.rti.org/sites/default/files/resources/finalreport_fdalabelingcostmodel_revisedoct2012.pdf
[47] Labeling Cost Model Report, p. 2-7.
[48] Labeling Cost Model Report, Table 2-1, page 2-8.

changes only to the following package-label types: paper labels, paperboard cartons, and paperboard cigarette cartons.[49]

Cigarette packs and cartons are not at all similar to the boxes of premium cigars. Soft packs of cigarettes are made of rotogravure printed paper, hard packs and cartons of cigarettes are made of rotogravure printed, thin paperboard.[50] However, many premium handmade cigars are packaged in sturdy paperboard or wood boxes that are silk-screen printed. The materials and methods for printing premium cigar boxes are nothing like the materials and methods for printing cigarette packs and cartons. Therefore, it is impossible to use FDA's labeling model to estimate the cost of changing labels on premium cigar boxes.

FDA was aware of the limitations of the labeling cost model when it began the Final Rule. In the Preliminary Regulatory Impact Analysis, FDA noted that the labeling cost model could not be used to estimate the number of cigar UPCs that would be affected by the rule and that therefore the agency would have to estimate the number of UPCs without using the labeling cost model.[51] FDA should have been aware of the limitations of the model for estimating the cost of relabeling per UPC. Nowhere in its analyses does FDA admit that its relabeling cost estimates are based only on the cost of changing cigarette labels. Nor does FDA offer any justification for why the cost of changing labels on cigarette packages is a reasonably-acceptable proxy for estimating the cost of changing labels on other tobacco products, especially premium cigars.

Moreover, the labeling cost model is designed to estimate three components of a labeling change: label design costs, inventory costs, and testing costs.[52] That approach works well for all of the products that FDA regulates except for premium cigars. Premium cigars are different from all of the products regulated by FDA. No food, cosmetic, or over-the-counter drug, for example, is a luxury-experience good where the packaging is an integral part of the product. The packaging for all of the products that FDA regulates act almost exclusively as containers for the product and surfaces to display information for consumers. As such, when FDA regulations alter the appearance of such packages, it is not significantly altering the product that the consumer is purchasing. Thus, FDA can make the assumption that it typically makes for its labeling rules of foods, drugs, and cosmetics: "We assume that the package size stays the same and the non-warning information is compressed to fit the reduced allotment of space. We assume that there are minimal costs to consumers from this compression of information."[53]

The agency's deeming of jurisdiction over premium cigars imposes a regulatory regime that is suited for canned corn or bottles of contact lens solution onto a luxury-experience product where it is ill-suited. If FDA is going to regulate luxury-experience products, then it must consider all of the impacts of its rules on them.

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[49] Labeling Cost Model Report, Table 2-1, p. 2-8.
[50] 75 Fed. Reg. 69548 (November 12, 2010), footnote 12.
[51] PRIA, p. 42.
[52] Labeling Cost Model Report, Chapter 3.
[53] FRIA, footnote 45.

On luxury-experience products, where the packaging is part of the product, packages are more than merely surfaces for warning and non-warning information. "Compression" of the "non-warning information" on luxury-experience packages actually defaces the packages and imposes significant costs on consumers. Premium cigar boxes serve as displays for the cigars. They serve as presentation packaging for special gifts. The polished wood, the stylishly-designed decoration, the size and shape of the boxes all contribute to the luxury-experience that is part of the experience of premium cigars. Additionally, long after they are empty of cigars, the boxes also have value to collectors and others who appreciate design, style, and craftsmanship in containers.

An accurate estimate of the cost of a regulation requiring that thirty percent of the principal display panel be covered with a warning must include these two additive cost aspects to consumers.

The Rule Will Not Reduce the Number of Cigars Smoked

There can be no public health benefit of implementing the rule for handmade cigars, because consumers of handmade cigars will not smoke significantly fewer cigars.

Decreases in consumption are usually caused by price increases. FDA does not "expect much increase in price due to variable costs being passed on."[54] And FDA claims that, "Most of the costs of the proposed rule are fixed costs, which affect prices [only] through product exit."[55] However, FDA did "not predict the effects of this rule on price, partly because estimating the price increase of newly deemed products due to product consolidation or exit is not straightforward."[56] In fact, there are so many handmade cigars on the market, and the industry is so competitive, that even with the reduction in the number of products that the rule will cause, producers are unlikely to significantly raise prices in response to the rule.

Additionally, handmade cigar smokers generally do not consume many cigars or spend a significant portion of their discretionary income on cigars. According to a survey conducted by Cigar Aficionado magazine in May 2009, 43 percent of respondents smoke two or fewer cigars per week and 36 percent reported smoking 3-6 cigars per week. At that level of consumption, handmade cigar smokers are not going to be very sensitive to limited changes in price. As Zheng, et al. show, if the particular cigar preferred by a handmade cigar smoker is not available, it is likely that the customer will choose to smoke another handmade cigar that is available or will choose to smoke a machine-made cigar or loose tobacco in a pipe.[57] FDA even repeatedly makes this point in the Final Regulatory Impact Analysis in

[54] FRIA, p. 46.
[55] FRIA, p. 18.
[56] FRIA, p. 18.
[57] Zheng, Y., Zhen, C., Dench, D., and Nonnemaker, J. M. (2017) U.S. Demand for Tobacco Products in a System Framework. Health Econ., 26: 1067–1086. doi: 10.1002/hec.3384.

responses to comments on the proposed rule.[58] At most, the Final Rule will cause there to be fewer *types* of cigars available, but not fewer cigars overall. Covering handmade cigars with the Final Rule will not reduce smoking and therefore provides no public health benefit.

Finally, throughout the history of this rulemaking, FDA has never attempted to estimate any health benefits that would result from this rule, even though FDA has been able to estimate public health benefits for other tobacco regulations.[59] We can only conclude that FDA chose not to report an estimate of benefits because the estimates were too low.

Conclusion

This report has relied on FDA's own estimates of the cost of the Final Rule to answer FDA's questions on the implications of the rule for the handmade cigar industry.

Compliance with the regulation will be so difficult and costly that it threatens to put almost all U.S. handmade cigar manufacturers and importers out of business. *Using FDA's own cost estimates*, the regulation likely will cause 85 to 90 percent of domestic cigar manufacturers and importers (320-338 small businesses) to go out of business, leading to the loss of 5,300 U.S. manufacturing and importing jobs. Because handmade cigars have the highest cost of compliance per cigar, almost all of the cigar manufacturers and importers that go out of business because of this rule will be manufacturers and importers of handmade cigars. The expected reduction in the number of handmade cigars on the market due to the rule is also likely to cause the closure of at least 494 tobacco retailers and the loss of as many as 19,800 U.S. retail jobs.

The business and unemployment consequences of the Final Rule for the handmade cigar industry are all the more painful because covering handmade cigars with the rule will not contribute to the stated goal of the regulation, "to reduce death and disease from tobacco products."[60] FDA acknowledges as much when it states that the rule will not have much effect on consumers because smokers will have plenty of tobacco alternatives if their preferred product is not available.[61]

Under Executive Order 13771, if agencies reduce regulatory burdens, they may apply the cost savings against future regulations. If FDA exempts handmade cigars from the Final Rule, then FDA could apply that is the amount that FDA could apply $197.8 million (discounted at 3%) under Executive Order 13771 toward other rulemakings that could promote and protect public health.

[58] FRIA, pp. 44 and 47.
[59] For example, see 75 Fed. Reg. 69546 (November 12, 2010) and 76 Fed. Reg. 36728 (June 22, 2011).
[60] 81 Fed. Reg. 28975 (May 10, 2016).
[61] FRIA, pp. 44 and 47.