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Director Shaun Donovan
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Administrator Howard Shelanski
Office of Information and Regulatory Affairs
725 17th Street, NW
Washington, DC 20503

Re: Docket FDA-2014-N-0189

Director Donovan & Administrator Shelanski:

The International Premium Cigar & Pipe Retailers Association (“IPCPR”) submits this letter following up on our recent meeting in Washington, DC where we spoke about the Food and Drug Administration’s (“FDA’s”) 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, 79 Fed. Reg. 23,142 (Apr. 25, 2014) (the “proposed deeming regulation”). Per your request, we have compiled information and data to further support our position on the proposed deeming regulation and outline the potential impact this rule could have on small businesses and U.S. domestic jobs.

In the proposed deeming regulation, FDA provided two options. In Option 1, all tobacco products, including premium cigars, would be regulated the same. Under Option 2, FDA proposed a definition of “premium cigars,” and then would exempt this small category of tobacco products from most regulation. IPCPR strongly opposes Option 1, and supports a slightly modified Option 2 as explained in our comments submitted to the FDA docket on August 7, 2014 (“IPCPR FDA Comment”). As explained in more detail in IPCPR’s Citizen Petition (FDA-2011-P-0623), the scientific research demonstrates that the typical premium cigar consumer is exposed to significantly lower health risks compared to cigarettes both quantitatively and qualitatively. Furthermore, as explained in the IPCPR Citizen Petition, premium cigars are not used to a significant extent by adolescents. Only Option 2 acknowledges these differences between premium cigars and all other tobacco products, and proposes to regulate premium cigars differently in accordance with their reduced effect on the public health. Because premium cigars pose lower health risks than cigarettes and lack significant youth access, FDA’s resources are better spent on regulating tobacco products that present more significant public health problems.

Organizational Background

IPCPR, based in Washington, DC, is a not-for-profit trade group representing premium cigar and tobacco retail stores located throughout the United States and abroad. IPCPR, formerly the Retail Tobacco Dealers of America (“RTDA”), was established in 1933. The typical IPCPR member’s store is a small business focusing almost exclusively on premium cigars, humidors, cutters, lighters, pipes, pipe tobaccos, and other related accessories. In recent surveys conducted during registration of the IPCPR trade show and by email to our membership, 64% of member stores respondents indicated that premium cigars make up 70% or more of sales. Over 47% of respondents to the same survey specify that greater than 80% of their sales are premium cigars. IPCPR members’ businesses are adult establishments, with 87% of IPCPR members in the United States having age restrictions for entry to the store; the remaining 13% having age restrictions on cigar areas, such as the walk-in humidor or cigar lounge. Unlike other tobacco retail channels, our retail members’ stores rely on the continued sale of tobacco to stay in business. If a tobacco store owner loses a tobacco sales license due to an illegal sale, it is nearly impossible to stay in business. As a result, compliance with local, state, and federal tobacco age restrictions is a top priority for each IPCPR member.



Small Business Demographics and Domestic Jobs

In the recent IPCPR member survey, 91% of cigar stores in the United States are family owned and operated, and have been open for an average of 17 years. The oldest cigar store in the United States, however, has been open for 158 years. Located in Chicago, Illinois, the original business owner's grandson, Chuck Levi, owns the same tobacco shop, Iwan Reis & Co. Our members have a strong tradition of compliance with laws to ensure that youth are not being provided access to any tobacco product.

With over 5,000 retail tobacco stores throughout the United States, IPCPR estimates our small businesses represent 27,500 to 35,000 domestic jobs. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors, and service providers. While this represents a large number of jobs, we are truly small business, accounting for a minor percentage of overall tobacco sales in the United States.

Indeed, the Small Business Administration ("SBA") has been instrumental in the success of our business owners, with over 25% of the current Board of the IPCPR having used an SBA loan to support their business. Through these federally sponsored loan programs, our Board members have grown their businesses, purchased new stores and HQ buildings, and created jobs throughout the United States, thus contributing significantly to the economies of local communities.

Consolidation of the Industry under Regulation

It is likely, if the proposed FDA regulations are implemented without change, that the premium cigar industry will see a major consolidation. Many smaller manufacturers will go out of business due to the crippling compliance costs of new product registration or substantial equivalence testing. Currently, there are no laboratories capable of constituent testing for premium cigars, and the costs associated with any potential testing will be devastating for manufacturers. As smaller companies are bought out, the industry will centralize, destroying the current competition, creativity, and consumer choice in the marketplace. This shift will make it even harder for small businesses to enter the market or compete with larger entities. As a result, many cigar retailers will suffer since they rely on boutique brands, blends, and seasonal releases to attract customers to their brick and mortar stores. Consumers will have fewer premium cigars to choose from. Eventually, monopoly power will drive consumer prices higher due to decreased competition and increased costs of regulatory compliance. Ironically, the proposed



regulations and related compliance costs has the likelihood to drive the premium cigar segment into the hands of big tobacco. Sales will move from Main Street businesses that have a demonstrated track record of keeping minors out of their stores and into the convenience store/gas station/drug store retail channels. We believe that a combination of lost jobs and greater youth access will result.

The Customer

In a recent IPCPR survey, over 87% of respondents reported the age range of their most frequent buyers to be over 35 years old. Usage data shows that premium cigars products are consumed infrequently, often in a celebratory nature, by adults. Premium cigars are also used at a much lower rate than cigarettes, smokeless tobacco, or non-premium cigars. According to a survey conducted by Cigar Aficionado magazine in May 2009, 43% of respondents smoke two cigars or less per week and 36% reported smoking 3-6 cigars per week (survey data on file). In contrast, most cigarette smokers, for example, smoke several times every day.

IPCPR's Annual Trade Show

In 2015, IPCPR hosted the 83rd annual IPCPR Trade Show and Convention in New Orleans, LA. This generated \$16 million in direct and indirect spending for the city. The show also generated \$1.4 million in state and local taxes for Louisiana. About 1,900 retailers were in attendance, representing approximately 745 retail stores from around the United States. In addition, 3,213 manufacturer associate members attended and exhibited at the trade show, while over 150 other individuals were categorized as media, distributors, or suppliers. Our 2014 annual IPCPR Trade Show and Convention was held in Las Vegas, NV, and provided similar benefits to the state and local economies.

Under Option 1, which restricts sampling of premium cigars and pipe tobacco, this trade show would cease to exist. The retailers' ability to sample new products from many different manufacturers is an integral part of the trade show. Without a trade show, other small businesses within the cities we visit will suffer economic harm. The show is also IPCPR's largest source of revenue. If sampling were banned, there would be little reason for retailers or manufacturers to attend the show and thus IPCPR would likely cease to exist in its present form. As explained in more detail below, this would leave a small business industry fragmented and without a centralized source of education as to compliance and best practices.



Definition of “Premium Cigar” & “Covered Cigar”

The definition of a “covered cigar” is of critical importance to FDA, manufacturers, importers, distributors, retailers, and consumers. FDA investigators (and/or their state counterparts), as law enforcement agents, must be able to determine whether a cigar is a “covered cigar” subject to greater regulatory restrictions, and which cigars are exempt as “premium cigars.” Manufacturers control the process of creating the cigar and the different types of tobacco leaf used in the production of these products. Thus, manufacturers have the greatest ability to determine whether a product meets the proposed exclusionary criteria when it leaves the factory. Retailers are largely dependent on the representations made by manufacturers, but are ultimately responsible for how the product is sold, including the retail price. However, retailers and manufacturers (as well as distributors and importers) bear potential legal liability if a “covered cigar” is improperly sold as a “premium cigar.”

IPCPR’s views on each of the eight proposed elements of a “covered cigar” (or “premium cigar”) were discussed in detail in the IPCPR FDA Comment. Briefly, some of the elements of the proposed definition (wrapped in whole tobacco leaf; has no filter, tip, or non-tobacco mouthpiece; and weighs more than 6 pounds per 1000 units) are easily visualized, allowing FDA and other government inspectors, retailers, importers, distributors, and consumers to readily identify the type of product at issue. Other elements will present more of a challenge for both enforcement and compliance. Whether a premium cigar “contains a 100 percent leaf tobacco binder,” or “primarily long filler tobacco,” is “made by combining manually the wrapper, filler, and binder,” and “is capped by hand,” can be difficult to determine. Should these elements become part of the definition of a “premium cigar,” a retailer must be able to rely on a manufacturer’s representation that the product meets the specified manufacturing requirements. Under those circumstances, IPCPR supports these components of the definition.

In contrast, IPCPR opposes a specified minimum price for a premium cigar (i.e., “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”). There are several problems with including an explicit cost in the definition of a “covered cigar.” The chief difficulty is that retail cost is controlled primarily by retailers. For example, if a retailer sells a cigar for less than \$10 that the manufacturer intended to be “premium,” would the manufacturer have then made a “covered cigar?” This could expose the manufacturer to legal liability. A second difficulty is that sales tax



rates and “other tobacco product” (“OTP”) or excise tax rates vary greatly between states. Those excise taxes range from three to 40.5 cents per ten cigars (Alabama) to nothing (Florida) to ten percent of the manufacturer’s price (Missouri) to 95 percent of the wholesale price with a \$3.50 tax cap (Minnesota). These variances, both in amount and in the timing of the assessment, affect the retail price of a cigar, resulting in a great variance in retail price between states for the same cigar. In addition, retail price of all goods is affected by geography, since retail prices tend to be higher in large cities than in rural areas. Thus, some cigars will be designated based solely on where they are sold. IPCPR is not aware of a specific retail price being an element of regulation by FDA of any other product, even cigarettes, and FDA has not explained why it is appropriate to target premium cigars. Finally, the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (“Tobacco Control Act”), includes this restriction on retailer records: “The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.” 21 U.S.C. § 387t(b)(5). It is not clear how FDA would enforce a retail price element given this apparently general prohibition.

Youth Access is Not a Significant Issue for Premium Cigars

IPCPR believes that age restriction and verification requirements currently established by state and local regulation are sensible regulatory steps for all tobacco products, including premium cigars sold face-to-face in our members’ stores. IPCPR is proud of our organization’s and our individual member’s constant efforts to help prevent underage access to tobacco products. Every member of IPCPR is offered free courses through Tobacconist University, IPCPR’s Official Education Provider, to become a Certified Retail Tobacconist. The very first obligation under The Code of Ethics & Standards for a Certified Retail Tobacconist is to: “Obey and enforce all local, state and federal laws regarding tobacco age/use restrictions.”

It should be recognized that the purchase or attempted purchase of tobacco products by minors is not a significant issue for premium cigar shops. Firstly, the premium products sold at IPCPR shops are generally not affordable to youth. Secondly, sales in our members’ stores are a face-to face transaction, and in the rare event that an adolescent might try to purchase a tobacco product from a cigar store, the salesperson (frequently the owner of the store) is required to verify the age of the customer. In addition, each new member of IPCPR receives a “We ID” package of signage to use at the point of sale. Thirdly, our members’ shops are subject to state and local regulation of tobacco sales, which have proven more



than adequate to control underage access to tobacco products from our members' establishments. Fourthly, the recent No-Tobacco-Sale Order released by FDA on October 29, 2015 did not include a single premium cigar retailer or member of our Association. IPCPR is proud of the compliance record of its members. As FDA noted in the proposed deeming regulations, the Office of the Inspector General for the Department of Health and Human Services ("OIG") has concluded that minors are not attracted to premium cigars, but prefer lower cost and more readily accessible tobacco products. 79 Fed. Reg. at 23,151 (quoting OIG, Youth Use of Cigars: Patterns of Use and Perceptions of Risk, OEI-06-98-00030 (Feb. 1999)).

Limited Editions, Seasonal Releases, and Sampling Events are Essential to the Survival of the Small Retail Cigar Business

Retailers rely on boutique blends, limited editions, and seasonal releases to drive customers into their stores. By offering unique products that often can't be bought through other channels, customers seek out retailers to find out "what's new". The requirement for pre-market review and substantial equivalence testing will not allow manufacturers to create new products because the barrier to entry into the marketplace and costs associated will be too high. This retail channel is incredibly important to the survival of our small businesses.

In a recent IPCPR survey, over 95% of retailers host sampling events for new products in-store allowing customers to experience the cigar. Customers often speak directly with manufacturers about the cigars before committing to a purchase. This is one of the largest traffic drivers to these adult-only establishments.

In regards to sampling events, the FDA states "The Institute of Medicine (IOM) has stated that free samples of cigarettes 'encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity' (Ref. 26). As IPCPR has explained to FDA on several occasions, the same rationale does not apply to premium cigars. In contrast to the historical distribution of free cigarettes, sampling of premium cigars most frequently occurs in a controlled environment, namely, the tobacconist's shop. The professional tobacconist controls who is provided the sample, and requires proof of age. Unlike cigarette smokers, premium cigar smokers exhibit little brand loyalty and "sampling events" are frequently held in premium cigar shops as social occasions to introduce adult premium cigar smokers to limited edition products, seasonal offerings, new brands and varieties, and promote the shop. Often, these sampling events are tied to local community



charities. A ban on such practices would have an immediate and significant adverse effect on many small businesses.

The Blending of Pipe Tobacco in a Retail Store Should Also be Exempt from Regulation

In a recent IPCPR survey, 86% of cigar stores sell pipe tobacco. Many retailers create unique blends of pipe tobacco specific to their stores, but the proposed deeming regulation would consider them to be “manufacturers”, even if the pipe tobacco used was purchased as a regulated product. Blending tobacco that has already been regulated should not require retailers to register as manufacturers. FDA should establish a “safe harbor” for retailers blending an aggregate of up to 5,000 pounds of pipe tobacco per year. FDA established a retailer “safe harbor” for required warning labels and advertising on cigars in the proposed deeming regulations, and FDA should apply the same logic to the retailer’s ability to continue the long-standing practice of providing custom blended pipe tobaccos to their adult customers.

Member Case Study – John Anderson, W. Curtis Draper Tobacconist and Civil Lounge

John Anderson serves on the Board of Directors for IPCPR and will soon be installed as our National President. He operates W. Curtis Draper Tobacconist and Civil Cigar Lounge in Washington, DC and Bethesda, MD. His business has always been employee owned and operated for 127 years, established in 1888. Among his three stores, he employs 30 people in the Washington, DC metro area. As a tobacconist, father, and representative of the IPCPR he fully supports restricting youth access to tobacco products. No person may enter any of his three stores if they are under 18. In all locations, customers must provide a valid form of identification. His products are not priced attractively to youth – cigars start at \$4.00 and go up. Many of his customers are buying cigars for a celebratory occasion, such as a round of golf, a new baby, a wedding, a special weekend, or any other celebration. John notes that the premium cigar experience (cutting, lighting, the aroma, etc.) people to slow down and relax, with premium cigars often lasting at least 45 minutes or more.

Member Case Study – Greg Zimmerman, The Tobacco Company

Greg Zimmerman serves on the Board of Directors for IPCPR and currently operates The Tobacco Company, with locations in Harrisburg, PA and Lemoyne,



PA. Greg's family business started 21 years ago and he currently employs 9 people, not including himself and his business partner. His regular customers include blue collar workers, doctors, lawyers, judges, people searching for employment, firemen, policemen, members of the military, and other demographics all linked by their desire to smoke a premium cigar. These individuals commonly discuss a wide variety of topics including politics, news and current events, sports, families, and all other areas of daily life. Greg describes his store as the modern day version of the barber shop or general store. Under 'Option 1', Greg estimates over 70% of his inventory could be eliminated. Over 90% of Greg's sales are premium handmade cigars, and like all of our members, he is concerned about how FDA regulation could negatively impact his small business and the individuals that he employs.

Conclusion

IPCPR member stores are small business tobacco retailers, catering to adults seeking an artisanal product which is not attractive or accessible to youth. We employ tens of thousands of people throughout the United States; FDA regulation under 'Option 1' would severely impact the ability of these retailers to continue doing business and would likely force closure of many stores and our annual trade show would cease to exist in its current form. A modified 'Option 2' is a much more sensible approach to regulation and keeps many small business job creators operational.

Sincerely,



Mark Pursell
Chief Executive Officer



R. Craig Cass
President

