NORTON ROSE FULBRIGHT

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

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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

Dear Commissioner Gottlieb:

The Norton Rose Fulbright firm represents the International Premium Cigar and Pipe Retailers Association ("IPCPR") and Cigar Rights of America ("CRA"). At the direction of those two organizations, this comment is jointly submitted on behalf of IPCPR and CRA in response to the FDA's request for comments and information regarding the appropriate definition of premium cigars, the health effects and usage patterns of premium cigars, and whether and how premium cigars should be regulated by the FDA. As explained in further detail in Appendix A, IPCPR is the Nation's leading organization for retailers of premium cigars, representing approximately 3,000 stores across the country, and Cigar Rights of America represents the Nation's leading premium cigar manufacturers as well as consumers of premium cigars, counting members in all 50 states. Both organizations have an intense interest in ensuring that the regulation of premium cigars does not threaten the livelihoods of premium cigar manufacturers and retailers, as well as access by premium cigar consumers to the quality and variety of products they expect.

EXECUTIVE SUMMARY

Premium cigars are different than other tobacco products, including other cigars. If properly defined, they are made by hand, from whole tobacco leaf, and contain no additives. The premium cigar manufacturing process—the absence of any mechanization—makes the products expensive. That same handmade construction process leads to many different varieties of premium cigars, depending on expert, discretionary blending to reach a particular taste profile.

The agency asked for evidence regarding the patterns of usage and health effects of premium cigars that was not available in the process leading to the deeming rule, and it abounds. The evidence submitted with this comment demonstrates that premium cigars are used differently than other tobacco products. Analysis of the Population Assessment of Tobacco and Health ("PATH") Study—including Wave 3, which became available only in recent months—has provided the data necessary to track the usage patterns of premium cigar consumers and to show the profound divergence from how other tobacco products are used.

First, premium cigar consumers use the products very infrequently. The Wave 1 PATH data from 2013–14 show that the median consumer of premium cigars uses the product 1.4 days per month. That number has only dropped in subsequent waves, with Wave 3 PATH data from 2015–16 showing median use of only 1.3 days per month. The percentage of premium cigar consumers who use the product daily is small. Wave 1 data showed only 5.1% of premium cigar consumers use the product daily; Wave 3 data showed only 3.5%. When measured against the 0.48% of adults who use premium cigars in Wave 3, that means only 0.0168% of American adults are using premium cigars daily. The comparison with consumers of cigarettes is dramatic: The median consumer of cigarettes uses the product a steady 29.4 days per month; between 76%

and 80% of cigarette smokers use cigarettes every day. Consumers of non-premium cigar products also use those products far more frequently than premium cigars.

These frequency data demonstrate that premium cigars simply are not being used to feed a nicotine addiction, but instead as a special occasion, luxury product. If the agency truly is "plac[ing] nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts," this usage pattern evidence shows that premium cigars should be at the far periphery of the agency's new focus.[1]

Second, the new evidence shows that premium cigar consumers are not among the Nation's most vulnerable, whose protection has long been the aim of government regulation. Following on previous studies, analyses of all waves of the PATH data confirm that there is no measurable problem of youth usage of premium cigars. By Wave 3, the PATH data showed that only 0.02% of youth ages 12–17 smoked premium cigars and could not find a single person aged 12–14 who used premium cigars. In Wave 3, the median age of first use of premium cigars was 29.8 years old, compared against 16.7 years old for cigarettes. Instead, premium cigars are consumed by older, better-educated, and higher income adults. Of the 0.48% of American adults who consume premium cigars, 56.0% graduated from college and 45.4% had annual household incomes in excess of $100,000. As explained in further detail below, these premium cigar demographic statistics are markedly divergent from those for cigarette and non-premium cigar consumers.

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[1] Press Release, FDA, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

These radical differences in usage patterns between premium cigars, on the one hand, and cigarettes and non-premium cigars, on the other, show that premium cigars are not just part of one big problem of tobacco use. Instead, they show that the regulatory scheme designed for cigarettes, and recently extended to all cigars, is not appropriate for premium cigars. The Government should treat premium cigars differently. The right policy outcome is to exempt premium cigars from the coverage of the deeming rule and to focus agency attention on those tobacco products whose usage patterns show significant use to feed an addiction to nicotine and present evidence of youth initiation and use. Taking aspects of the current regulatory scheme in turn conclusively demonstrates that, as a whole, it is entirely unsuited to premium cigars.

First, the premarket and substantial equivalence review process makes no sense for premium cigars. The definition of premium cigars proposed herein will ensure that each premium cigar is made in the same way cigars have been made for centuries. Each will be made by hand, from all natural tobacco. None will have any artificial additives. And none will be a novel product that the agency should expend resources examining. In short, the premarket review and substantial equivalence process will not benefit the public health in any meaningful way.

At the same time, premarket and substantial equivalence review of premium cigars will impose massive costs on the industry and the agency. The process will be dramatically more expensive for premium cigars than for cigarettes and non-premium cigars because of the vast variety of premium cigar products. This springs from the very character of premium cigars, the use of all natural tobacco and the variations that ensue from weather and terroir, and their crafting by hand. The industry estimates that there are 20,000 premium cigar products, as compared against dozens of main products for the cigarette and non-premium cigar industries, whose machines and volume consolidate the market into a handful of products. And the costs of

substantial equivalence review will be directly proportional to the number of separate products. Some premium cigar manufacturers will fold, and many premium cigar products will exit the marketplace. These events will have everything to do with the financial resources required to survive the process and nothing to do with the public health. Beyond the effects on American small businesses, review of premium cigars will consume scarce agency resources and expertise that would be better directed at tobacco products used with a frequency indicating service of a nicotine addiction and posing a significant threat to the public health.

Second and related is the 2019 constituent testing requirement. Consistent with the agency's July 28, 2017, announcement, the principal purpose of constituent testing is to gauge the extent to which the product conveys nicotine. But the usage pattern data show that premium cigars are not being used with a frequency designed to feed a nicotine addiction. At the same time, the technology for testing a premium cigar does not currently exist. If it were somehow to be created (and it certainly will not be for years), it would yield inconsistent and useless results; handcrafting and natural tobacco renders every premium cigar different, even within the same box.

Third, the massive health warnings covering 30% of two sides of each box and 20% of each advertisement have no place in the premium cigar market. They will impose staggering expenses in the redesign of thousands of packages and hundreds of thousands of manufacturer and retailer communications with consumers. If left in place, wooden boxes that often graced a grandfather's desk will be forever marred by a glaring black-on-white message of danger. They will be the largest and most intrusive government-compelled warnings in American history. But there is no need for these warnings on premium cigars, as there is no evidence that they will reduce any existing problem. Premium cigars are not being used by children in any measurable numbers. And their consumers are significantly better educated and higher-income than the

average American, much less the average user of cigarettes or non-premium cigars. Surveys show that there is not a misunderstanding regarding the health effects of abusing cigars, and premium cigar consumers are using the products sparingly. These warnings on premium cigars defy common sense and will fail the serious scrutiny that the Supreme Court has just demanded for government-compelled speech. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018). The agency should exempt premium cigars from the warnings requirements as well as the rest of the deeming rule.

At the beginning of this administration, President Trump ordered agencies to take a serious look at revoking regulations that are imposing significant costs of private business while yielding few public benefits. The deeming rule's application to premium cigars is the poster child for carrying out the President's instructions. The evidence contained herein shows that premium cigars are not being used by youth or being used frequently by adults. At the same time, the agency's regulation threatens the continued existence of small businesses that populate the premium cigar industry. As premium cigar manufacturers take products off the market rather than pay tens or hundreds of thousands of dollars for each product's substantial equivalence review, constituent testing, and packaging redesign, the 400,000 workers in the premium cigar industry in Nicaragua, Honduras, and the Dominican Republic will be displaced. This economic pain in Central America will only exacerbate the crisis at our Nation's border, which the Administration is attempting to resolve through difficult enforcement decisions. Saving jobs in Nicaragua and Honduras will prevent attempted migration in the first place.

In light of this new evidence, the agency should modify the deeming rule and its attendant user fees rule to exempt a properly defined category of premium cigars from

regulation. Doing so will save businesses and jobs and will allow the agency to focus on tobacco products that are being abused and do threaten the public health.

A. Premium Cigars Can Be Defined as a Class of Tobacco Products and Significantly Differ from Non-Premium Cigars and Other Tobacco Products

Premium cigars significantly differ from non-premium cigars and other tobacco products. They are made by hand, from whole tobacco leaf, and contain no additives. The process of manufacture ensures that premium cigars are more expensive than other types of cigars. It also ensures that premium cigars are not innovations meriting close scrutiny through government regulation. The criteria for premium cigars set forth below confirm that each premium cigar will be made as they have been for centuries, before the age of automation, artificial additives, and chemical engineering. When premium cigars are properly defined, casting premium cigars into a painstaking, product-by-product premarket or substantial equivalence review process to identify dangerous innovations in tobacco products makes no sense.

1. *Data Sources for Identifying Premium Cigars and Defining the Characteristics of Premium Cigars*

The FDA has asked how premium cigars should be defined and distinguished from non-premium products and what data sources are available to support that definition. We believe that the FDA was on the right track when it proposed a definition of premium cigars for potential exemption from regulation in its 2014 proposed rule.[2] We endorse that definition but propose that the FDA delete the minimum retail price requirement and slightly modify the characterizing flavor term.

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[2] *See* 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).

Our proposal would modify the FDA's definition of premium cigars as follows (added words are italicized; deleted words are struck through):

> A cigar that (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) ~~has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7)~~ does not ~~have~~ *contain an additive that is* a characterizing flavor other than tobacco; and ~~(8)~~ *(7)* weighs more than 6 pounds per 1,000 units.

As explained in further detail below, the above proposal makes two revisions to the FDA's proposed definition of premium cigars. First, it eliminates the requirement of a minimum retail price. That requirement is both unnecessary and impractical. It is unnecessary because the required manner of manufacturing premium cigars—by hand, from whole tobacco leaf—ensures that premium cigars will be considerably more expensive than machine-made, non-premium cigars. Second, a minimum retail price requirement will be virtually impossible to administer and to enforce. After all, the most onerous aspects of the regulatory scheme, including premarket or substantial equivalence review, fall on manufacturers, who must know what regulatory scheme will govern their products when they are made. That is impossible if the regulatory scheme turns on the price at which a downstream retailer will sell a cigar. These and other defects in a minimum retail price requirement are discussed in sections o and p below.

Second, the proposal modifies the characterizing flavor term to focus on additives to the all-natural tobacco leaf that has long constituted a premium cigar. This change is meant to focus on the manner in which the product is manufactured and to avoid confusion with later descriptions of a product's taste profile by retailers or reviewers, much as reviewers attempt to describe the taste notes in a fine wine entirely made of grapes with such descriptive terms as

"leather" or "cedar." We understand that other parties may urge the inclusion of products with flavor-imparting additives in the definition of premium cigar, but CRA and IPCPR seek to disaggregate the treatment of premium cigars from the FDA's separate inquiry into flavored tobacco products and to underscore the all-natural character of premium cigars.

The definition will have two consequences important for advancing the public health. First, it will encompass a very small number of tobacco products. Premium cigars account for only 2.9% by volume of the entire cigar market. All cigarettes account for roughly 250 billion units sold every year.[3] As explained below, extensive data, including from the Government's PATH Study, show that premium cigars are used infrequently, by older, better-educated, and higher-income adults.

Second, this definition will prevent other tobacco products from recasting themselves as premium cigars. That non-premium cigars and tobacco products are made by machines is crucial to their role in the marketplace, particularly with regard to their price. It is inconceivable that a company could transform the manufacturing process of a machine-made cigar into one made entirely by hand and from all natural and expensive tobacco, while remaining economically viable. The required manner of manufacturing for premium cigars will serve as a crucial barrier to entry into the premium category of products that rely on high-speed machines and inexpensive ingredients.

As discussed in greater detail below, these unique characteristics of premium cigars lead to different usage patterns than any other tobacco products. While regulating the extremely small

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[3] *See Economic Trends in Tobacco*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm (last updated May 4, 2018).

premium cigar industry will require extensive effort and expense by the agency, there will be very little benefit to the public health.

Below we further explain why and how certain factors have been included in our proposed definition and certain factors have been excluded, organized along the agency's specific requests for information in the ANPRM.

a. Size (*e.g.*, length, ring gauge, total weight).

We agree with the FDA's proposal to address the size of a premium cigar by setting a minimum weight. For federal excise tax purposes, "large cigars" are defined as weighing more than 3 pounds per 1,000 units.[4] In its original proposed definition of premium cigars, the FDA went above the excise tax threshold and set a minimum weight of 6 pounds per 1,000 cigars. We support the FDA's approach and believe that 6 pounds per thousand units is an appropriate definitional term. This weight threshold will be an additional, externally verifiable, mechanism against the migration of machine-made products into the premium category.

The minimum weight requirement also would place a large gulf between the appearance of cigarettes and premium cigars and thus provide yet another protection against any consumer confusion between cigarettes and premium cigars. While some non-premium cigars are so small that they can be confused with cigarettes, the same simply is not true of premium cigars. Using weight as the appropriate measure of size also would ease administration of the premium cigar definition, as it is relatively straightforward to verify.

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[4] *See* 26 U.S.C. § 5701. We note that "large cigars" are further distinct from "premium cigars," as large cigars may or may not be handmade, use filters, contain added flavors, or possess any of the other characteristics of premium cigars discussed herein.

Any specification for premium cigars based on their size should be focused exclusively on their weight per 1,000 units. As explained above, premium cigars are made by hand. In the experience of premium cigar craftsmen, it is very difficult to make a cigar fully by hand with a weight less than *9* pounds per thousand. We would be open to such an increase. But we oppose any specification of other size parameters for premium cigars, such as ring gauge or length. The minimum weight requirement, in addition to the requirement for manual combination of the wrapper, binder, and filler and capping the cigar by hand, will prevent the creation of premium cigars similar in size to cigarettes. In addition, because premium cigars are made by hand, their ring gauges and lengths vary within even the same box. Given the variations in the handmade production process, measuring weight across 1,000 products is the most consistent and administrable method for regulating the size of those cigars qualifying as premium.

b. Tobacco filler type and minimum required percentages of each filler per cigar.

We endorse the FDA's proposed requirement that a premium cigar contain "primarily long filler tobacco." As used in the premium cigar industry, "long filler tobacco" refers to cigars consisting primarily of whole tobacco leaves that run the length of the cigar. Short filler tobacco, by contrast, refers to scraps of tobacco leaf that tend to burn quicker and hotter than long filler tobacco and are the primary tobaccos used for mass-marketed, machine-made products. Given the quality of the tobacco leaf, long filler tobacco is also more expensive than short filler tobacco. When combined with the requirement of hand construction, the long filler mandate ensures that premium cigars will be relatively expensive.

The FDA also was correct to qualify the "long filler tobacco" requirement with the word "primarily." Some premium cigars contain small amounts of short filler tobacco, albeit 100

percent whole leaf tobacco, because the hand construction process inevitably breaks small portions of the leaves. In addition, long filler tobacco can break apart after assembly, either naturally in dry climates or in transit or handling. This in no way affects the quality of the tobacco. The requirement that a premium cigar contain "primarily" long filler tobacco accommodates these types of situations and is more readily administrable than a minimum required percentage. Importantly, it also acts as a barrier to entry for non-premium products, as the expense and manual labor entailed in using primarily long filler tobacco effectively prevents non-premium manufacturers from transforming their products into premium cigars.

c. Fermentation type.

The 100 percent whole leaf tobacco used in premium cigars is fermented naturally and slowly. This process, called "air curing," is markedly different than the process used for fermenting tobacco found in other products. Unlike in other combustible tobacco products, the natural fermentation process for premium cigar tobacco is a process that relies only upon the naturally occurring heat caused by the moisture and pressure of the tobacco leaves themselves. During the natural fermentation process, the tobacco is stacked by hand in piles, actively monitored, and then repeatedly disassembled, rotated, and restacked, and often has additional water applied to control the temperature and rate of fermentation. Premium cigar makers do not use any chemicals to adjust the fermentation process.

The tobacco used in premium cigars is further naturally fermented for long periods—from several weeks to sometimes as many as 6–18 months, or even longer. This natural and time-consuming manual process further ensures that premium cigars will be more expensive to manufacture than other tobacco products.

If the FDA wishes, the industry is prepared to work with the agency to find a description of the fermentation process that could be included in the definition of a premium cigar. Any such term, however, should not include a minimum duration of fermentation. Fermentation periods can vary significantly based on a variety of factors including the tobacco leaf's position on the stalk, level of thickness, and final use (e.g., whether used for the wrapper, binder, or filler). Because of these variations, any duration requirement would be difficult to administer and could have unintended consequences.

d. Wrapper and binder composition (*e.g.*, whole leaf, reconstituted or homogenized tobacco leaf).

The FDA's proposed definition requires that a premium cigar be wrapped in whole tobacco leaf and contain a 100 percent leaf tobacco binder. We strongly endorse both requirements. We are proud that premium cigars are made from all-natural, 100 percent tobacco leaf, both wrapper and binder, and contain no additives. The requirement that a premium cigar be wrapped in whole tobacco leaf specifically excludes products with a reconstituted tobacco or homogenized tobacco wrapper.

The requirement also ensures that premium cigars will be more expensive. Whole tobacco leaf wrappers are far more expensive than reconstituted or homogenized tobacco wrappers. Grown in the Connecticut River Valley, Cameroon, Honduras, Nicaragua, the Dominican Republic, and other microclimates, the wrappers are in very high demand compared to their supply. And the extremely delicate nature of whole tobacco leaf prevents its use on high-speed machines. Together, the cost of whole tobacco leaf and the need for manual composition erect a practically insuperable barrier to entry of non-premium cigars into the premium category, as they would price out their customer base.

In addition, a whole tobacco leaf wrapper is visually identifiable, without any sophisticated training or analysis. Accordingly, the FDA and other agencies, inspectors, retailers, distributors, importers, and consumers can readily identify the product type.

e. Where the tobacco used for premium cigar filler or wrappers is grown, and whether differences in growing practices for that tobacco, as compared to tobacco used in other cigars, result in different health impacts.

The FDA's proposed definition of premium cigars appropriately omitted a requirement based on where the tobacco is grown or the agricultural practices for growing that tobacco. The geographic source of the tobacco grown for the premium cigar filler or wrapper, and the different growing practices for each type of tobacco used in premium cigars, should not be considered among the defining characteristics of the products.

Tobacco for premium cigars imported into the United States is primarily grown in the Dominican Republic, Honduras, and Nicaragua, given the precise climates required for truly premium cigars. That said, there are certain microclimates in the United States (e.g., Connecticut), South America (e.g., Brazil), Asia (e.g., Indonesia), and Africa (e.g., Cameroon) that can produce wrapper or filler tobacco for a premium cigar. Each location's terroir and climate contributes to a unique flavor and aroma profile for the tobacco grown there, which master artisans blend to create the premium product that consumers demand. Often a single premium cigar will source its tobacco for its filler, wrapper, and binder from different locations. Changes in weather and growing conditions require these premium cigar manufacturers constantly to adapt and to vary the tobacco used in their products. Manufacturers will find the best tobacco grown in a particular season, and adjust the tobacco blend to maintain a consistent product and flavor. Similarly, each grower employs unique proprietary growing practices, often developed to suit the requirements of the particular terroir or weather. Manufacturers also offer

limited-run and seasonal products, effectively honoring the uncontrollable, unreplicable variations in the growing process. Because of the vast differences in geographic sources of tobacco and growing practices, even within a single premium cigar brand or blend, these characteristics should not be considered for the agency's current purposes.

With regard to growing practices in particular, there is no history in the premium cigar industry of manufacturers manipulating their growing practices to affect the nicotine content of their cigars. Instead, the selection of tobacco leaf for any given premium cigar is based entirely on artisan factors (*e.g.*, taste, aroma, smoothness/harshness), grower relationships, and supply chain considerations. As a result, any requirement of or against certain growing practices would be an artificial overlay on, rather than a description of, the premium cigar industry. Moreover, there is no evidence that the prospect that certain tobaccos may have different naturally occurring nicotine levels, or that certain growing practices may affect a tobacco crop's nicotine content, will result in different health impacts. As explained in greater detail elsewhere in this comment, premium cigars are not used in a manner consistent with using the product for nicotine delivery.

f. Presence or absence of a filter.

g. Presence or absence of a mouthpiece.

We combine our response to sections f and g below. We further endorse the FDA's requirement that premium cigar have "no filter, tip, or non-tobacco mouthpiece and [be] capped by hand." This is an absolutely crucial part of keeping premium cigars all natural and without any artificial additives or features. After all, the cardinal principles of premium cigars are that they are made wholly from leaf tobacco, by hand, with no additives. By contrast, filters, tips and non-tobacco mouthpieces are used by manufacturers of mass-marketed cigars and appeal to

consumers who are looking for an inexpensive product similar to cigarettes. Filters also can result in higher smoke inhalation rates and are therefore excluded from premium cigars.

Like the other proposed criteria for premium cigars, this requirement is easily administered and enforced. The absence of a filter, tip, or non-tobacco mouthpiece on a premium cigar will assist FDA and retailers, distributors, importers, and consumers in identifying the product as a premium cigar.

h. Manufacturing and assembly process (*e.g.,* including any production by hand or by machine).

Several aspects of the FDA's proposed definition of cigars ensures that they are made by hand, including the requirement that it be made by "combining manually the wrapper, filler, and binder" and that it be "capped by hand." We wholeheartedly endorse these requirements. Hand-crafting is the essence of a premium cigar. Premium cigars are assembled by the hand of skilled artisans. By definition, the entire manufacturing and assembly process for premium cigars is a non-standardized process requiring the uninterrupted involvement of experienced tradesman throughout. This long and painstaking process takes two to five years or more, from the planting of the tobacco seed, to the harvest, to the cultivation of the natural wrapper, to the rolling of the cigar. During this time there can be as many as 300 separate manual steps. Unsurprisingly, hand making a cigar that requires hundreds of manual steps and continuous human input results in a premium product that is significantly more expensive than a product produced by a machine that can generate thousands of units. It also results in each hand-crafted cigar being unique, as human beings do not replicate each step identically with each cigar, but instead craft each cigar in line with the condition and character of the particular tobacco leaves used. This

manufacturing process bears no relation to the machines churning identical cigars off the assembly line.

Manual assembly of the wrapper, filler, and binder by hand is the hallmark of premium cigar manufacturing for good reason. First, due to fragile and delicate nature of the product's high quality tobacco components—namely, the whole tobacco leaf wrapper, the 100 percent leaf tobacco binder, and the long filler tobacco—premium cigars cannot be produced on high-speed machines like cigarettes or non-premium cigars. Second, unpredictable weather and growing conditions require manufacturers to regularly blend and reblend tobacco leaf to maintain the taste and character of a sub-brand from year to year, a process that cannot be duplicated by machine.

The labor-intensive, unmechanized process of producing premium cigars ensures that no two are entirely alike, and guarantees that premium cigars will be more expensive than mass-marketed products. The requirement that premium cigars are made by manually assembling the wrapper, filler, and binder by hand further prevents non-premium manufacturers, who rely on machines, from quickly and easily transforming their products into "premium cigars" to avoid regulation.[5]

i. Rate of production (*e.g.,* ''produced at no more than [insert number] units per minute'').

[5] We understand that the J.C. Newman Cigar Company is seeking an exception from the handmade requirement for centuries-old, hand-operated machines at their domestic plant in Ybor City, Florida. We support this proposed exception, so long as it is strictly limited to this historic facility, which is integral to the local economy and is a significant source of manufacturing jobs. The aspects of handcrafting set forth in this comment, represented in our proposed modifications to the "Option 2" definition and acknowledged in J.C. Newman's own comment, are core features of a premium cigar that defend the category from mechanized and mass-marketed cigars and should otherwise be strongly enforced.

As discussed in section h, the manufacturing and assembly process for premium cigars is a slow, manual process requiring continuous expert input. As a result, the rate of production of premium cigars is drastically lower than the production rate for mass-marketed products that roll off assembly lines. A skilled artisan handcrafting a cigar is no match for a machine in terms of speed. We respectfully submit, however, that the FDA was correct not to include a maximum rate of production in the definition of premium cigar, because the manual construction requirement ensures a painstaking and lengthy process.

j. Presence or absence of flavor imparting compounds, flavor additives, or characterizing flavors other than tobacco.

The FDA proposed requiring that premium cigars "not have a characterizing flavor other than tobacco." We have proposed a clarification of that restriction, that the cigar "*not contain an additive* that is a characterizing flavor other than tobacco." Alternatively, the agency could prohibit any additive other than cigar glue, as suggested in section k below. This proposed clarification is designed to avoid any declassification of an entirely natural, 100 percent leaf tobacco cigar as a premium cigar based on descriptions of the product's taste profile after the fact, such as in publications like *Cigar Aficionado*. With that clarification, we endorse that requirement that excludes from the category of premium cigars any product that is composed with an artificial, non-tobacco additive that imparts a flavor to the tobacco. This requirement would be focused on ensuring that premium cigars are made only of natural tobacco and obviates any need to study premium cigars—through a premarket review process—regarding the health effects of any additive.

We recognize that the use of artificial flavors in tobacco products generally is a matter that the FDA has chosen to study further, opening an Advance Notice of Proposed Rulemaking

to gather evidence and information regarding their effect on public health and possible regulatory solutions.[6] Premium cigars, defined as proposed by the FDA to exclude additives to the cigar to impart a flavor, need not be a part of this inquiry. We also recognize that the FDA may wish to examine, through premarket review or otherwise, the marginal effect that a flavor-imparting additive might have on issues concerning the public health. We do not wish for premium cigars to be caught in the FDA's internal decision-making process about how to regulate flavor-imparting additives.

Instead, premium cigars made of whole tobacco leaf and rolled by hand would be constructed as cigars have been centuries. They create no novel public health issues, and they reflect Congress's judgment that products similar to those on the market before 2007 should be subject to special protection. To be sure, the 100 percent natural leaf tobacco used in premium cigars is grown in diverse geographic locations, with distinctive weather, soil and growing conditions. These elements contribute to thousands of types of premium cigars with unique flavor and aroma profiles. Consequently, while premium cigars do not contain any "flavor additives," premium cigar reviewers will still commonly describe the taste profile of premium cigars that are comprised of 100 percent natural leaf tobacco by using terminology referring to complex flavors other than "tobacco." This practice is similar to wine reviewers describing the complex flavors of wine with terminology other than just "grapes." And it is consistent with practices in the premium cigar industry for centuries. Accordingly, the agency's focus should be on flavor-imparting additives. Our proposed adjustment will ensure that a product can be classified based on how it is manufactured, rather than the *post hoc* observations of others, as

[6] Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,294–301 (Mar. 21, 2018).

reviewers or downstream retailers potentially characterize a complex-tasting product as "bitter," "bold," "earthy," "notes of chocolate or coffee," etc.—even if nothing has been added to the natural tobacco in the cigar.

k. Presence or absence of any additives other than cigar glue.

Premium cigars consist only of natural tobacco leaf, water, and a small amount of plant-based adhesive. Unlike other tobacco products, premium cigars contain no artificial additives like ammonia, freon, or other chemicals. As explained in section j above, we are proud that premium cigars only contain natural tobacco and the plant-based adhesive to hold the cigar together, known as cigar glue. There is no question that one purpose of premarket review is to examine how particular artificial additives interact with tobacco. Prohibiting additives other than cigar glue in premium cigars would further obviate the need for applying the cumbersome and expensive premarket review mechanism to premium cigars. While we believe that the flavor additive restriction almost entirely addresses this issue, we would be open to a restriction on "artificial additives other than cigar glue."

l. Nicotine content.

m. Tar delivery amounts (and how this should be defined and measured).

n. Carbon monoxide delivery amounts (and how this should be defined and measured).

We combine our response to sections l, m, and n below. We do not believe that nicotine content, tar delivery amounts, and carbon monoxide delivery amounts should be part of the definition of a premium cigar. Doing so would effectively set a nicotine standard for premium cigars, which we do not believe is warranted. In particular, the evidence presented herein about

premium cigar usage patterns shows that they are not being used as a nicotine delivery system.[7] In addition, the premium cigar industry has no history of manipulating its product to deliver a particular amount of nicotine. To do so would be entirely contrary to the process of constructing a premium cigar, which involves crafting the product by hand, from natural tobacco, to a particular taste profile. None of this occurs in a laboratory, as might have been part of the history of cigarettes. Requiring premium cigar manufacturers to craft their products to a nicotine target, in order to qualify, would destroy all the features of premium cigar construction that set it apart. For further reasons not to adopt a nicotine standard for premium cigars, please see our comments in response to the rulemaking docket concerning a nicotine product standard, incorporated by reference herein and attached hereto as Exhibits 1 and 2.

These same arguments counsel against incorporating tar or carbon monoxide delivery amounts in the definition of a premium cigar. Again, such a definition would force companies to artificially manipulate their product and would destroy the features of the premium cigar construction process that set them apart from other tobacco products. It would also effectively impose a testing requirement on premium cigars. For the reasons discussed in Part C.3.b below, the testing requirement currently applicable to premium cigars is impossible to implement and totally impractical.

o. Retail price.

p. Frequency with which price changes are initiated by particular levels in the distribution chain (retailers, manufacturers, importers, and/or distributors).

We combine our response to section o and p below. Premium cigars are a premium product that command a premium price. As discussed, premium cigars' high-quality tobacco is

[7] *See* Part B. Use Patterns of Premium Cigars, *infra*.

more expensive than the ingredients used in mass-market products, which are designed specifically to keep prices lower. The whole leaf wrapper and the long filler tobacco used for premium cigar products are substantially more expensive than the reconstituted homogenized tobacco paper and short filler tobacco used for mass-marketed cigars. Further, the labor-intensive process for manufacturing and assembling premium cigars by hand requires hundreds of manual steps and continuous human input by skilled artisans, ensuring that premium cigars are significantly more expensive than machine-made products. All of these requirements will prevent non-premium products from entering the category with their price-sensitive consumers. High retail price is an important feature of premium cigars; we nonetheless recommend eliminating the minimum price requirement. It is impractical and impossible to administer.

First, manufacturers of premium cigars do not control retail prices; that decision is entirely up to the retailers who set prices on premium products for various commercial reasons unique to the particular retailer that often have nothing to do with whether the product is a premium cigar. Including a minimum retail price in the definition of premium cigars places the power of whether to designate a product as a premium cigar entirely in the retailers' hands, *after the fact*, regardless of the enormous efforts undertaken by manufacturers to create a product that meets the proposed definition of premium cigars. This is an especially perverse result as most of the regulatory requirements—including premarket review, registration, product and ingredient listings, and inspections—apply to manufacturers. Manufacturers need to know that their product will be considered a premium cigar *when it is manufactured*, not when it is sold.

Second, prices for the same premium cigars can fluctuate drastically between locations where they are sold, making reliance on retail price to help define premium products unworkable. Each state has different excise tax or "other tobacco tax" rates affecting retail

prices. For example, state excise taxes are 40.5 cents per ten cigars in Alabama, 10% of the manufacturer's price in Missouri, and 75% of the wholesale price in New York.[8] Although the New York City Department of Health and Mental Hygiene's (the "DOHMH") comment in response to this ANPRM is misguided in its opposition to exempting a class of premium cigars from these regulations, it persuasively argues that "a federally established price point based on retail price to determine what constitutes a premium cigar would be complicated by price variation among jurisdictions."[9] That comment uses New York City's "novel" scheme of "taxes and minimum price laws to increase cigar prices," and how that scheme differs from other jurisdictions, to illustrate the practical problems with a definition of premium cigars that includes a retail price component.[10]

In addition to the effect of different tax schemes, the downstream practices of individual retailers on price may result in the same premium product being sold at different prices, even in the same state or city. For example, different retailers may set different retail prices based on factors such as the geographic location of their store, store rents or whether the seller is based on the Internet only. Retailers may also have commercial reasons for offering selected premium products at cost or below cost on a permanent or temporary basis.

Third, requiring premium cigars to be characterized by a minimum retail price would threaten to strand premium products that are not selling as well as intended, by prohibiting

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[8] Fed'n of Tax Admr's, *State Taxes on Other Tobacco Products* (2018), *available at* https://www.taxadmin.org/assets/docs/Research/Rates/otp.pdf.
[9] Comment from N.Y.C. Dep't of Health & Mental Hygiene at 2, ID No. FDA-2017-N-6107-6476 (July 12, 2018), *available at* https://www.regulations.gov/document?D=FDA-2017-N-6107-6476.
[10] *Id.*

retailers from discounting the products as they deem appropriate, or from running sales and other promotions, often at prices below cost.

Fourth, the $10 per cigar price point chosen by the agency is far afield and unsupported. When FDA staff took a serious look at premium cigar usage patterns and published their results, they chose a $2 per cigar price point to capture as premium cigars situations when survey respondents could not remember or did not specify the brand.[11] This threshold, which was not used as a limitation on the premium brands identified, produced the usage and demographic results reported by FDA staff and discussed below.

Plainly, retail price is not a useful or workable metric to determine whether a product should be defined as a premium cigar, and we are unaware of any other product that enters or exits a federal regulatory scheme based on its retail price. Instead, the process required by the proposed definition ensures that handmade, premium cigars will be more expensive, without the administrative problems of manufacturers' attempts to determine whether their product is a premium cigar based on the future downstream practices of retailers. The natural market forces in play that keep premium cigars more expensive than mass-produced cigars are sufficient to distinguish premium cigars without including price as a defining characteristic.

q. Packaging quantity and size.

[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 3 (attached hereto as Exhibit 3).

r. Any action 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.

We combine our response to sections q and r below. Advertising and marketing of premium cigars differs drastically than that for cigarettes, mass-market cigar brands, and other tobacco products. Premium cigars are sold predominantly in specialty retail shops or through specialty mail order companies, where age verification is required to prevent sales to minors. This stands in stark contrast to mass-produced cigars and cigarettes, which often are displayed behind the counters of convenience stores and other retailers that are accessible to minors.[12] Furthermore, premium cigars generally are sold in ornate packages and distinctive boxes that communicate a message of luxury and craftsmanship and often are viewed as collector's items in their own right. The designs, symbols, and trademarks found on the distinct cigar boxes send a message to consumers about the qualities of the products and the craftsmanship with which they were made. Those boxes additionally provide consumers with information about the rare tobacco used and the qualities of the product.

However, advertising and marketing, as well as the quantity contained in each package and the size of the packaging, should not be considered in the determination of whether a product is defined as a premium cigar. While premium cigar manufacturers generally control various aspects of advertising and marketing—including the decision to market the product as a luxury good targeted to older, better-educated, and more affluent individuals—manufacturers have no

[12] *See id.* at 6 tbl.3 (reporting that nearly 77% of premium cigar consumers purchased premium cigars in cigar bars or specialty tobacco stores, while 75% of filtered cigar users, 79% of non-premium cigar users, 85% of cigarillo users, and 87% of cigarette users purchased those products in convenience stores or gas stations).

control over how retailers will advertise or market their premium brands. Instead of relying on advertising and marketing, the significantly higher price of premium cigars as compared to cigarettes, mass-market cigar brands, and other tobacco products as well as the taste profile and traditional usage of premium cigars, ensures that manufacturers' target customer base is who purchases premium cigars.

Toggling regulation based on how a product is advertised would also trigger First Amendment issues, as it would assign dramatic expenses to speech about a product. As the Supreme Court noted in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001), Constitutional protections apply with full force to speech regarding tobacco products because, "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information."[13]

Quantity of cigars in a package or the size of a package also is not a defining characteristic of premium cigars. Consistent with the low frequency of their use, premium cigars can be sold as a single cigar wrapped only in a clear wrapper or in packages or boxes of any number of cigars. If reducing tobacco use is the objective of regulation, it would be counter-productive to force consumers to purchase 10 or 25 premium cigars at a time, leaving the excess immediately at hand for future use. Because they are handmade, premium cigars do not come in a uniform size; instead, they come in a functionally endless variety of shapes, sizes, and lengths.

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[13] *See also Thompson v. Clark*, 741 F.2d 401, 405 (D.C. Cir. 1984) (when a "defective regulatory flexibility analysis cause[s] an agency to underestimate the harm inflicted upon small businesses to such a degree that . . . th[e] harm clearly outweighs the claimed benefits of the rule, . . . then the rule must be set aside").

B. The Usage Patterns of Premium Cigars Demonstrate That Premium Cigars Are Different from Other Cigars and Cigarettes

The FDA has requested studies and information related to the use patterns of premium cigars generally, and among youth and young adults specifically, that were unavailable during the Deeming Rule's comment period. Through the several expert reports attached to this comment, we have compiled that evidence. The data clearly show that youth simply do not use premium cigars, that the small segment of adults who are premium cigar consumers use the products very infrequently, and that premium cigar consumers are older, higher-income, and better-educated than other tobacco product consumers.

From the opening of this administrative docket, the agency cited as the model example of data needed a study conducted by the FDA's own staff and led by Catherine Corey.[14] That paper, as the FDA explained, found that "cigar smoking patterns and tobacco use behaviors varied by cigar type," and that there are "clear distinctions between premium and non-premium smoker characteristics, use patterns and purchasing behaviors."[15] The paper analyzed the Wave 1 of data collected in 2013–2014 from the FDA Center for Tobacco Products' Population Assessment of Tobacco and Health ("PATH") Study, which is an ongoing, "nationally representative, longitudinal cohort study of 45,971 adults and youth in the United States."[16] The PATH Study collects information about the types of cigars and brands used, allowing comparisons to be drawn between premium cigars and other tobacco products.[17]

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[14] 83 Fed. Reg. at 12,902 (citing Corey et al., *supra* note 11).
[15] Corey et al., *supra* note 11, at 1, 4 tbl.1.
[16] *Id.* at 2.
[17] *Id.* at 3.

Dr. Corey's work shows "clear distinctions" between usage patterns for premium cigars and other cigar types and cigarettes.[18] According to Dr. Corey, the overall adult prevalence of premium cigar usage is dramatically lower than that of cigarettes.[19] The median age of first regular use of premium cigars is well into adulthood (rather than during youth), and much older than for other cigar types or cigarettes.[20] And those adults who are current users of premium cigars tend to be substantially older, better-educated, and of higher income than users of other cigar types or cigarettes, and to purchase their cigars at specialty shops or cigar bars rather than at gas stations or convenience stores.[21] Premium cigars are also consumed far less frequently than other cigar types or cigarettes, with the median consumer of premium cigars using the product 1.7 days per month and 93.3% using the product less than daily.[22] In addition, those using premium cigars are much less likely than those using non-premium cigars also to smoke cigarettes.[23]

Through this comment, we are adding substantially to the published analysis of PATH data. NERA Economic Consulting ("NERA") has analyzed the from PATH Wave 1 data and newly available data from PATH Wave 2 (2014–15) and PATH Wave 3 (2015–16), and sets forth its conclusions in a report submitted with this comment (the "NERA Report," attached

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[18] *Id.* at 1.
[19] *Id.* at 4 tbl.1 (0.7% for premium cigars versus 18.1% for cigarettes).
[20] *Id.* at 5 tbl.2 (24.5 years for premium cigars versus 16.6–19.5 years for non-premium traditional cigars, cigarillos, and cigarettes).
[21] *Id.* at 4 tbl.1, 6 tbl.3 (57% of adult premium cigar consumers were over the age of 35, 73.8% of adults age 18 and older had completed at least some college or earned an associate degree, and 62.7% had a household income exceeding 200% of the federal poverty level).
[22] *Id.* at 5 tbl.2 (93.3% of premium cigar users versus 62.7–78% of users of non-premium traditional cigars, cigarillos, and filtered cigars, and 20.5% of cigarette users); *Id.* at 5 tbl.2 (1.7 days out of past 30).
[23] *Id.* at 7 tbl.4 (29.9% for premium cigars versus 59.5% for non-premium traditional cigars).

hereto as Exhibit 4).[24] This analysis identifies premium cigar usage patterns that are strikingly distinct from those of other tobacco products. NERA's work is the first study of which we are aware to analyze the data from PATH Waves 2 and 3; indeed, the data from PATH Wave 3 became available for the first time *within the last 90 days*.

In addition, submitted with this comment is a report from Econsult Solutions (attached hereto as Exhibit 5) analyzing data collected from five major online premium cigar retailers. As explained below, that analysis provides further evidence of high age, income, and education of premium cigar consumers, as well as their low frequency of use.[25]

The studies provide compelling new evidence that premium cigars are different from other tobacco products in ways important to public health. Premium cigars are not used as nicotine delivery devices by youth or adults, but rather as luxury goods reserved for occasional indulgence primarily by older and better-educated adults. Nor are premium cigars used to initiate tobacco use or as a gateway to cigarettes. Moreover, the defining features of premium cigars—especially their all-natural and handmade character, which ensure a comparatively high price[26]—make it extremely unlikely that manufacturers of non-premium cigar products or cigarettes would transform them into premium cigars in the event premium cigars were exempted from regulation. For all these reasons, premium cigars should not be subject to the same regulatory scheme as other cigars.

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[24] NERA Report at ¶¶ 4-6.
[25] Econsult Report at 2–5 (describing scope of work and methodology).
[26] Indeed, Dr. Corey calculated the median price per premium cigar to be $7.49, compared to $1.00 for each non-premium cigar and cigarillo, $0.27 for each cigarette, and $0.12 for each filtered cigar. Corey et al., *supra* note 11, at 6 tbl.3.

As requested in the ANPRM, set forth below are specific data and information concerning premium cigars and (1) tobacco initiation and progression; (2) dual use; (3) frequency and intensity; (4) symptoms of dependence; (5) abuse liability; (6) the impact of labeling, advertising, and marketing efforts; and (7) the extent to which users of other tobacco products might switch to premium cigars if the FDA were to exempt or differently regulate premium cigars.

1. *Tobacco Initiation and Progression*

NERA's analysis confirms that premium cigars do not play a meaningful role in tobacco initiation among youth. The overall youth prevalence of premium cigar use was almost imperceptible for all three PATH Study waves and declined over time from 0.08% in Wave 1 to 0.02% in Wave 3,[27] as detailed in Table 1 from the NERA Report, reproduced here[28]:

[27] NERA Report at ¶ 25–26, tbl.1.

[28] NERA used the same definition of "premium cigar" as used by Dr. Corey. Implementing that definition, Dr. Corey classified specific brands as premium from the list of brands used, as identified by the PATH Study participants. Working with undersigned counsel, NERA discovered several brands that Dr. Corey had misclassified as premium cigars and other brands that had been identified in the PATH Study data that were clearly premium cigars, but had not been treated by Dr. Corey as such. This resulted in reclassifying nine cigar brands as non-premium that Dr. Corey had erroneously classified as premium and classifying 36 brands as premium that Dr. Corey had omitted from the premium category. NERA Report at ¶¶ 18–22. Importantly, Dr. Corey included several brands as premium cigars that have additives imparting a characterizing flavor and that, as a result, would be inconsistent with the FDA's proposed definition of premium cigars and the definition proposed in this comment. NERA thus ran a parallel series of calculations excluding those brands with flavor-imparting additives and reported those results in the tables, under the title "unflavored premium traditional cigars." We use those statistics in this comment to align with our proposed definition of premium cigars, while noting that they do not differ in any statistically meaningful way from the overall premium cigar results in the NERA analysis.

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.

Indeed, in Wave 3, there is only one current premium cigar user among the 11,814 PATH Study participants aged 12-17.[29] By comparison, overall youth prevalence was many times higher for cigarillos (1.17-0.35%) and cigarettes (3.25-1.77%).[30] The median age of premium cigar consumers at first regular use increased over the three waves from 24.8 years in Wave 1 to 29.8 years in Wave 3.[31] By Wave 3, the median age at first regular use of premium cigars was *13 years* older than the median age of first regular use among cigarette consumers, which had held steady at 16.6–16.7 years old across all three PATH waves.[32] NERA's findings are

[29] NERA Report at ¶¶ 7(i)(a), 26, tbl.1.
[30] NERA Report at ¶ 26, tbl.1.
[31] NERA Report at ¶¶ 49, tbls.5a–c.
[32] NERA Report at ¶¶ 49, tbls.5a–7.

consistent with a recent paper in the *New England Journal of Medicine*, which found that only 2.3% of youth had ever used a "traditional cigar"—the category in which that paper grouped premium and non-premium cigars—and the percentage of youth engaged in "frequent" or "daily" use of "traditional cigars" was so small that it could not be measured reliably.[33]

NERA confirms that premium cigars are used by older, better-educated, and higher-income adults. Among adults, the overall prevalence of premium cigar use hovers around one-half of one percent, starting at 0.51% in Wave 1 and dropping to 0.48% in Wave 3.[34] The median age of current established premium cigar users has increased over the 3 years covered by PATH's three waves, from 38.1 in Wave 1 to 46.0 in Wave 3.[35] In Wave 1, 57.9% of premium cigar consumers were older than 35; in Wave 3 that number was 65.7%.[36]

A far higher percentage of premium cigar users age 25 and older has completed college or beyond—46.4% in Wave 1 and 56.0% in Wave 3—than users of any other cigar type (e.g., 10.6–11.7% for cigarillo users) or cigarettes (11.9–12.3%).[37] That percentage for premium cigar consumers is also substantially higher than the 32.5% of all adult Americans aged 25 and older who have graduated from college.[38] Premium cigar users are likewise financially better-off,

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[33] 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 (2017), supp. app. tbls.S3, S4 (attached hereto as Exhibit 6).
[34] NERA Report at ¶ 28, tbl.2.
[35] NERA Report at tbls.5a–c.
[36] NERA Report at tbls.3a–c; *see also* Econsult Report at 9 (average age of premium cigar customer is 55 years old, with 88% of premium cigar customers over age 35).
[37] NERA Report at tbls.3a–c. We use the 25 and older statistic to allow participants the normal time necessary to complete college and to be consistent with the age cohort other scientists use to measure educational attainment in the United States.
[38] *See* Camille L. Ryan & Kurt Bauman, U.S. Census Bureau, *Educational Attainment in the United States: 2015* (Mar. 2016), *available at* https://www.census.gov/content/dam/Census/library/publications/2016/demo/p20-578.pdf (data from 2015 Current Population Report) (attached hereto as Exhibit 7).

especially in comparison to users of other tobacco products. In Wave 1, approximately 66.2% of adult premium cigar consumers had a household income exceeding 200% of the federal poverty level, significantly higher than the approximate percentages for users of non-premium traditional cigars (29.7%), cigarillos (22.6%), filtered cigars (18.4%), or cigarettes (32.3%).[39] Between more than a third and nearly one-half of premium cigar users (36.9–45.4%) have an annual household income in excess of $100,000, compared to only 8.8–13.4% of non-premium traditional cigar users, 5.8–9.5% of cigarillo users, and 7.5–7.7% of cigarette users.[40] That is more than double the 19.9% of U.S. households reporting annual income in excess of $100,000.[41] The pattern is reversed at the bottom of the income scale, with 40.6% of non-premium traditional cigar users, 47.1% of cigarillo users, 44.9% of filtered cigar users, and 34.2% of cigarette users falling below the poverty line, as compared to approximately just 12.7% of premium cigar users.[42]

The PATH Study data also demonstrate that premium cigar use does not lead to cigarette use, or what the agency refers to as "progression" to cigarette use. NERA found that only 2.3% of the adult premium cigar users who were not everyday cigarette smokers at the end of Wave 1 in 2014 had become everyday cigarette smokers by the end of Wave 3 in 2016, which compared with 9.1% for users of non-premium cigars, 11.5% for cigarillo users, and 26.4% for filtered

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[39] NERA Report at tbls.3a–c. Results reported for Wave 1. Household poverty status is not available from the PATH Study data Waves 2 and 3.
[40] NERA Report at tbls.3a–c.
[41] *See* Lam Thuy Vo, *What Americans Earn*, NPR (July 16, 2012), https://www.npr.org/sections/money/2012/07/16/156688596/what-americans-earn (calculating figure with 2010 Census data).
[42] NERA Report at tbls.3a–c. Results reported for Wave 1. Household poverty status is not available from the PATH Study data Waves 2 and 3.

cigar users.[43] That 2.3% figure for premium cigar users is not statistically different from the 1.1% of adult study participants who were not users of *any* combustible tobacco product at the end of Wave 1 but became everyday cigarette smokers by the end of Wave 3, indicating that premium cigar use results in negligible, if any, progression to everyday cigarette use as compared to the non-smoking population.[44] Similar results are obtained if progression into some day cigarette smoking is considered.[45]

2. *Frequency and Intensity*[46]

NERA's analysis confirms that premium cigars are used very infrequently and in a manner consistent with being an occasional luxury, rather than as vehicles for nicotine delivery. In Wave 1, the median adult consumer of premium cigars used them 1.7 days out of 30; by Wave 3, that number had dropped to 1.3 days out of 30.[47] And those one to two days per month are hardly a binge: The median premium cigar consumer averaged just 0.1 cigars per day in the past 30 days.[48] The comparison with other cigar types and cigarettes is stark. The median filtered cigar consumer smoked them on 12.8–14.5 days out of 30 and smoked 0.9–1.6 such cigars per

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[43] NERA Report at ¶ 51, tbl.6.
[44] NERA Report at ¶ 51, tbl.6.
[45] NERA Report at ¶ 52, tbl.7. Only 9 out of 138 premium cigar consumers who were not someday cigarette users as of Wave 1 (6.4%) became someday cigarette users by Wave 3, compared with 13.2% of non-premium cigar users, 17.3% of cigarillo users, and 29.5% of filtered cigar users. *Id.* Again, the figure for premium cigar consumers was statistically indistinguishable from the 2.5% of non-tobacco users at Wave 1 who became someday cigarette users by Wave 3. *Id.*
[46] We discuss NERA's analysis of the frequency of premium cigar use before discussing dual use of premium cigars and cigarettes because the frequency data inform the dual use data. We have structured the comment this way in the interest of avoiding repetition.
[47] NERA Report at tbls.4a–c.
[48] NERA Report at tbls.4a–c. For statistical purposes, Corey et al. assigned a value of 0.5 cigars per day to consumers that reported smoking less than one cigar per day on the days smoked. *See* Corey et al., *supra* note 15, at 5 tbl.2. NERA followed this methodology.

day, while the median cigarette consumer smoked cigarettes almost every day (29.4 out of 30 days) and smoked 9.8–10.1 cigarettes per day.[49]

Nearly all premium cigar consumers (from 93.1% in Wave 1 to 96.5% in Wave 3) use premium cigars less frequently than daily, and generally much less.[50] By Wave 3, only 3.5% of all premium cigar consumers used the product daily. That means 3.5% of the 0.48% of American adults in Wave 3 who consumed premium cigars used them daily; said another way, 0.0168% of American adults smoke premium cigars daily. As explained below, studies cannot link negative health outcomes to non-daily use by exclusive cigar consumers. Any evaluation of regulatory options for premium cigars will have to weigh the expense of regulation against the projected benefits for, including the chance regulation will change the behavior of, 0.0168% of American adults.

Again, the comparison with other cigar types and cigarettes is very significant. Nearly 15.6–22.0% of cigarillo users, 37.3–40.9% of filtered cigar users, and 76.0–79.5% of cigarette users smoke those products each and every day.[51]

The conclusion that the typical premium cigar consumer uses them only sporadically, as an indulgence or on special occasions, is reinforced by the actual sales data collected by retailers and analyzed in the Econsult Report. Among other things, these data show that 86% of consumers of premium cigars order them on fewer than ten occasions over a four-year period.[52]

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[49] NERA Report at ¶ 40–45, tbls.4a–c.
[50] NERA Report at tbls. 4a–c; *see also* Corey et al., *supra* note 15, at 5 tbl.2; Kasza et al., *supra* note 33, at supp. app. tbl.S4.
[51] NERA Report at tbls.4a–c; *see also* Corey et al., *supra* note 15, at 5 tbl.2.
[52] Econsult Report at 12.

Even the most frequent purchasers purchase premium cigars on average 6.9 times per year.[53] Reflective of premium cigars' status as special occasion items and gifts, premium cigar orders are clustered during limited times of year, including in and around Father's Day, Christmas and Hanukkah, and summer vacation periods.[54]

3. *Dual Use of Premium Cigars and Other Tobacco Products*

NERA's analysis of the PATH data also demonstrates that premium cigars consumers are significantly less likely to use cigarettes than consumers of non-premium cigars. Over all three PATH waves, the median premium cigar consumer smoked cigarettes on zero days over a 30-day period.[55] The corresponding median number of days on which cigarettes were smoked over the same time period by consumers of all other cigar types was substantially higher—as high as 19.9 days among the non-premium subgroup of cigarillos, 29.0 days among the non-premium subgroup of traditional cigars, and 29.2 days among the non-premium subgroup of filtered cigars.[56] PATH Study data further show that between two thirds and three quarters of premium cigar consumers (69.9–76.0%) are not current established cigarette smokers, and in excess of a third of premium cigar consumers (34.7–40.4%) have *never* been established cigarette smokers.[57]

As to the minority of premium cigar consumers who are also current established cigarette smokers, that percentage dropped from 27.5% in Wave 1 to 24.0% in Wave 3.[58] Importantly, the category of a current established cigarette smoker is defined generously to include anyone

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[53] Econsult Report at 12.
[54] Econsult Report at 10.
[55] NERA Report at ¶¶ 57–59, tbls. 9a–c.
[56] NERA Report at ¶¶ 57–59, tbls. 9a–c.
[57] NERA Report at ¶¶ 57–59, tbls. 9a–c.
[58] NERA Report at ¶¶ 57–59, tbls. 9a–c.

having smoked 100 cigarettes in a lifetime and some cigarettes recently. This statistic compares dramatically to other non-premium cigar products, with 66.0–73.2% of filtered cigar consumers also counting as current established cigarette users.[59] No more than 10.2% of premium cigar consumers who also use cigarettes started using premium cigars at an earlier age.[60]

As for the current practices of dual users of cigarettes and premium cigars, the PATH data conclusively show that cigarette consumers are not coming to premium cigars as a nicotine delivery system to feed any nicotine addiction they might have. As explained further below, the median dual user of premium cigars and cigarettes consumes premium cigars less frequently than the median consumer of premium cigars who does not also use cigarettes—only 0.7–1.1 days per month as compared to 1.5–1.9 days per month for premium cigar users who are not current cigarette smokers.[61] Of those premium cigar consumers who also smoke cigarettes, only 4.5–5.8% consume premium cigars daily.[62] These data cannot be squared with use of premium cigars to supplement the delivery of nicotine otherwise obtained from cigarettes. If nicotine is driving frequent use and if consumers use a tobacco product frequently to feed nicotine addiction, the data show that dual users are not using premium cigars to obtain nicotine.

4. *Symptoms of Dependence*

[59] NERA Report at ¶¶ 57–59, tbls. 9a–c.
[60] NERA Report at ¶ 55, tbl.8. The PATH Study data do not indicate the brand of traditional cigars first used, so it cannot be determined whether that first traditional cigar was premium or non-premium. 78.8% of premium cigar consumers who also use cigarettes first smoked cigarettes rather than traditional cigars, 11.0% smoked cigarettes and traditional cigars for the first time at the same age, and 10.1% first used traditional cigars rather than cigarettes. It is possible that respondents first used traditional cigars, smoked cigarettes at a later age, and used premium cigars for the first time only recently. Thus, the percentage of premium cigar consumers who also use cigarettes, and who first smoked cigarettes rather than premium cigars, may be greater than 78.8%.
[61] NERA Report at ¶¶ 60–62, tbl.10a–c.
[62] NERA Report at ¶¶ 60–62, tbl.10a–c.

5. ***Abuse Liability***

We combine our response to sections 4 and 5 below. The foregoing evidence demonstrates that premium cigars are not driving or being abused to satisfy a nicotine addiction. Indeed, that the median consumer of premium cigars uses them far less than daily—in Wave 3 just 1.3 days out of 30—is the best possible evidence that those consumers are not using them to feed a nicotine addiction.[63] Premium cigars are simply not used with a frequency to make them an effective nicotine delivery system or in a manner consistent with addiction to the product. If used to feed a nicotine addiction, we would expect patterns of use closer to cigarettes, with the products being used every day (29.4 days out of 30 for the median consumer of cigarettes) or on most days.[64]

The dual use data only reinforce this conclusion. Those premium cigar consumers who also smoke cigarettes use premium cigars *less frequently* than premium cigar consumers who do not smoke cigarettes. The median dual user uses premium cigars 0.7–1.1 days per thirty. That very infrequent premium cigar use, in addition to the dual user's cigarette use, is contrary to such dual users consuming premium cigars as a supplemental nicotine delivery system. The actual behavior of that cohort shows the absence of premium cigars' abuse liability.

As discussed in Part C, below, the available epidemiological data are in accord. To take just one example, a 2017 *Drug and Alcohol Dependence* study partially funded by the FDA and co-authored by FDA staff found, based on PATH data, that cigar-only users showed the lowest mean indicators of tobacco dependence among users of all tobacco products—more than a full

[63] NERA Report at ¶¶ 60–62, tbl.10a–c.
[64] NERA Report at ¶¶ 60–62, tbl.10a–c.

standard deviation below the baseline for the cigarette-only reference group.[65] And this calculation included non-premium cigars. Had the methodology of this study been applied solely to premium cigars, we would reasonably expect several more standard downward deviations from the baseline of the cigarette-only group.

6. *Impact of Labeling, Advertising, and Marketing Efforts on Patterns of Use*

There is no evidence suggesting that the labeling, advertising, and marketing activities of premium cigar manufacturers and retailers are driving Americans to use, much less abuse premium cigar products. As an initial matter, there is no evidence that premium cigar advertising or labeling is designed to attract youth, and that is confirmed by the usage patterns, which show that youth usage of premium cigars is statistically indistinguishable from zero.[66]

With regard to adults, it is hard to contend that advertising, labeling, or marketing is drawing adults to consume premium cigars, much less to use them with great frequency. The prevalence of premium cigar use has only declined over the PATH waves, now sitting at 0.48% of adults.[67] Even among that small percentage of adult Americans, the median consumer of premium cigars used those products on fewer than two days a month, again a rate that declined from Wave 1 to Wave 3.[68] These patterns of use show that premium cigar advertising, labeling, and marketing are designed to provide information about the varieties of premium cigar products and help interested adults to choose among them, not draw them into the fold. Indeed, as Dr.

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[65] David R. Strong et al., *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*, 178 Drug & Alcohol Dependence 257, 257, 260 (2017) (attached hereto as Exhibit 8).
[66] NERA Report at ¶ 26, tbl.1; *see also* Kasza et al., *supra* note 33, supp. app. tbls.S3, S4.
[67] NERA Report at ¶ 28, tbl.2.
[68] NERA Report at tbls.4a–c.

Cecil R. Reynolds, a behavioral scientist with more than 38 years of clinical experience studying primarily youth and adolescents, explains in his expert report accompanying these comments (the "Reynolds Report," attached hereto as Exhibit 9), studies indicate that a tobacco product's label or advertising has very little to do with the decision to use tobacco products.[69] That conclusion is all the more likely to be true among the more educated and higher income consumers of premium cigars, who rely on advertising less to determine whether to use a product than to choose among the products in a category in which they are already seeking to make a purchase.

Moreover, such low usage rates for premium cigars translate into correspondingly low exposure to labeling and marketing. If a premium cigar consumer purchases a single box of cigars and smokes one or two days out of every thirty, he or she is exposed to the product's labeling and marketing no more than three times a month. Exposure is further limited by the marketing channels for premium cigars—predominantly high-end, adult-oriented publications that advertise other luxury goods to high-income consumers and age-restricted websites and specialty tobacco shops. As explained in the Reynolds Report, such minimal levels of exposure will make premium cigar labeling, advertising, and marketing ineffective in changing consumer behavior or educating consumers about purported health risks.[70] This compares against the product placement of non-premium cigars and cigarettes, where consumers are exposed to packaging (and any warning labels, for example, thereon) in stores while shopping for non-tobacco products. Also, because the retail channels for premium cigars are age restricted, exposure to the label for youth is minimal to non-existent.

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[69] Reynolds Report at 19–25.
[70] Reynolds Report at 12.

We explain in Part C, below, that applying large warning labels to premium cigars will have no meaningful effect on the initiation or continued use of premium cigars or other tobacco products, and we incorporate that discussion by reference here.

7. *Potential for Switch to Premium Cigars Were the FDA to Exempt Premium Cigars*

There is no evidence that users of other tobacco products might switch to premium cigars if the FDA were to exempt premium cigars from regulation, as we urge herein. As an initial matter, by defining premium cigars to require time-consuming and expensive manufacturing by hand from whole leaf tobacco, together with an enhanced weight requirement, the FDA would erect an insuperable barrier to any mass-market manufacturer attempting to transition its products into "premium cigars." Those same defining characteristics ensure a high price for premium cigars, which would keep them inaccessible and unattractive to any user of a tobacco product searching for a substitute means of nicotine delivery.

As detailed above, the existing entrenched use patterns and demographics of consumers of premium cigars should give the FDA further comfort that carving premium cigars out of these new regulations will not result in a significant defection to premium cigars by users of cigarillos, filtered cigars, or other covered tobacco products. Unlike other types of cigars, premium cigars are a niche product used by a small sliver of the adult population (with youth usage hardly distinguishable from zero) on a highly infrequent basis that is inconsistent with use for nicotine delivery or to satisfy an addiction.[71] Users of other cigar types are generally younger, less

[71] NERA Report at tbls. 1–2 and 4a–c; *see also* Corey et al., *supra* note 15, at 5 tbl.2; Kasza et al., *supra* note 33, at supp. app. tbls.S3, S4.

educated, and of lower income than consumers of premium cigars.[72] Unlike premium cigar consumers, non-premium cigar consumers are far more likely to engage in daily cigar use and dual use of cigarettes.[73] Nothing about the new regulations would make premium cigars more attractive to those users were premium cigars to be excused from them. After all, even if premarket review were applied aggressively by the agency, there are hundreds of fully grandfathered non-premium cigar products on the market.

In particular, there is no basis on which to conclude that exempting premium cigars from the new, larger health warnings would cause any user of a different cigar type to abandon his or her preferred product in favor of premium cigars. The most recent studies and data shows that there is not a misunderstanding regarding the health effects of all cigars, much less premium cigars.[74] Further, as Dr. Reynolds explains, no data exist to show that the FDA's larger warnings—or, by extension, their absence—will affect youth decisions about cigar usage, which are driven by a series of distinct risk factors (e.g., peers, personality traits, psychosocial influences, etc.).[75] All available evidence indicates that, if exempted from these new rules, premium cigars will continue to be used only by the same small cohort of cigar aficionados who now use them as occasional indulgences.

C. Public Health Considerations

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[72] NERA Report at tbls.3a–c.
[73] NERA Report at tbls.4a–c and 9a–c.
[74] Rebecca K. Bernat et al., *U.S. Adult Tobacco Users' Absolute Harm Perceptions of Traditional and Alternative Tobacco Products, Information-Seeking Behaviors, and (Mis)beliefs About Chemicals in Tobacco Products*, 71 Addictive Behaviors 38, 41 tbl.2 (2017) (attached hereto as Exhibit 10).
[75] Reynolds Report at 12–15.

Premium cigars are luxury goods that are purchased and used by adults with higher education levels and household incomes than consumers of other tobacco products. There is no measurable problem of youth usage of premium cigar products. Premium cigars also are not used in a manner that gives rise to increased mortality risks—or that even is indicative of nicotine addiction.

Against this backdrop, the regulatory scheme designed by Congress for cigarettes and recently applied by the agency to all cigars is manifestly ill-suited for premium cigars. The right answer is to exempt a properly defined category of premium cigars from regulation, along the lines set forth, with minor adjustments, in the agency's Option 2 proposal in 2015. A short review of how the regulatory scheme would apply to the types of products qualifying as premium cigars and the demographic and usage patterns above so demonstrates.

Most importantly, the crushing and entirely unnecessary expense of the premarket review and testing schemes makes no sense for premium cigars. This conclusion flows, in part, from the definition of premium cigars set forth in Section A of this Comment. Premium cigars are handmade, from whole tobacco leaf, and with no additives. *By definition*, each premium cigar is constructed as cigars have been for centuries. To the extent Congress contemplated premarket review for innovative products that would raise new public health problems, that scheme has absolutely no relevance to premium cigars. Moreover, there are no non-tobacco flavoring additives that need to be evaluated with each separate premium cigar, as the proposed definition firmly excludes such additives.

That premarket review should not apply to premium cigars also flows from the way premium cigars are used. As demonstrated above, premium cigars are not being used with a frequency that suggests their use as a nicotine delivery system. Again, in the latest wave of the

PATH Study, premium cigar consumers used the products 1.3 days per month and just 3.5% used the product daily.[76] To the extent that the agency envisions premarket review as a mechanism to render tobacco products less addictive, its attention is better directed at other tobacco products.

Finally, premium cigars present few to none of the serious problems of tobacco products but will consume *most* of the agency's resources. That is because of the intense variety in premium cigars: There are nearly 20,000 separate premium cigar products, a result of the hand crafting and small manufacturers at the core of the industry. Many of those manufacturers will throw in the towel when faced with the daunting costs of premarket review and testing, causing random product exit with no benefit for public health. But thousands of premium cigar products will be presented for premarket or substantial equivalence review, and processing those applications will bury the agency in unnecessary work. More ominously, the volume of reviewing premium cigar products—all of which are made, by definition, as cigars have been for centuries—will divert the agency's focus from other tobacco products with innovative additives, unknown public health effects, and presenting serious problems of abuse and addiction. Regulating premium cigars will set back the public health, not advance it.

The large warnings scheme also makes no sense for premium cigars and threatens our Nation's most sacred constitutional values. The warnings are truly massive: Black text on a white background covers 30% of the two principal display panels of a cigar box and 20% of virtually every consumer communication about a cigar. If allowed to stand, they will forever mar the elegant wooden boxes that are the hallmark of premium cigars and that have become

[76] NERA Report at tbls.4a–c.

keepsakes in their own right. The older, better-educated, higher-income adults who occasionally use premium cigars need not be bludgeoned with health warnings. Indeed, by using the products sparingly, premium cigar consumers are exhibiting behavior showing that they already understand the health risks of the products. There is simply not a sufficiently significant problem with premium cigars in need of correction through the largest government-compelled health warnings in American history. We also do not believe these warnings will survive constitutional scrutiny, especially in light of the Supreme Court's decision in *National Institute of Family and Life Advocates v. Becerra*.[77] As it readopts Option 2 and exempts premium cigars from its regulatory scheme, the agency should not pause over the consequences of sparing premium cigars from these wholly unjustified warnings.

1. *Premium Cigars Present Qualitatively Different Health Risks than Other Tobacco Products, Including Other Cigars*

In the most recent wave of the PATH Study, the median consumer of premium cigars uses them 1.3 days per month.[78] No wave of the PATH Study showed median usage more than 1.7 days per month.[79] In the last wave, only 3.5% of premium cigar consumers (which themselves comprise 0.48% of adults)—that is, 0.0168% of American adults or about 40,000 Americans—use premium cigars daily.[80]

A recent FDA-funded study published in the *Journal of the American Medical Association* ("*JAMA*") has concluded that non-daily exclusive cigar usage—characteristic of

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[77] *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (holding that disclosure requirements likely violated First Amendment and explaining that to survive scrutiny under *Zauderer* they had to "remedy a harm that is potentially real not purely hypothetical, and . . . extend no broader than reasonably necessary" (quotation marks omitted)).
[78] NERA Report at tbls.4a–c.
[79] NERA Report at tbls.4a–c.
[80] NERA Report at tbl.2 and tbls.4a–c.

96.5% of premium cigar consumers—does not lead to any statistically significant increase in mortality.[81] This study examined data from the Tobacco Use Supplement to the Current Population Survey linked to the National Longitudinal Mortality Study ("NLMS"), a nationally representative sample of the civilian, noninstitutionalized population dating back to 1973.[82] This study followed 357,420 Americans for 26 years, drawn from a pool of 640,726 NMLS participants who provided tobacco use information in surveys administered between 1985 and 2011.[83] The researchers estimated mortality risks stemming from daily and non-daily use of various tobacco products using "Cox proportional hazards models with age as the underlying time variable," with multivariable adjustments for sex, race/ethnicity, and other factors.[84] For each studied cause of death (all cause, all tobacco-related cancer, lung cancer, oral cancer, circulatory, cardiovascular, cerebrovascular, respiratory, COPD, and diabetes), the researchers calculated multivariable hazard ratios at 95% confidence intervals for non-daily exclusive cigar use—*and each confidence interval included the baseline of 1.0 for never tobacco users*.[85] The study, notwithstanding the hundreds of thousands participants, could not show a statistically significant increase in mortality or tobacco related diseases for persons smoking cigars less frequently than daily over the non-smoking population. Put another way, *if individuals use premium cigars as more than 97% of consumers do (i.e., less frequently than daily), the evidence*

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[81] *See* Carol H. Christensen et al., *Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population*, JAMA Internal Med., Feb. 19, 2018, at E1, E6 tbl.3 (attached hereto as Exhibit 11).
[82] *Id.* at E2.
[83] *Id.*
[84] *Id.* at E3.
[85] *Id.* at E6 tbl.3.

shows no statistically significant increased risk of mortality or other tobacco related diseases.[86] This comports with an epidemiological truism: That the dose of any product affects health outcomes.

In this way, the frequency with which premium cigar consumers use the product sets them apart from the consumers of other tobacco products. The agency's regulatory focus should be on products that are being used in any meaningful numbers with a frequency that creates a risk to health outcomes. They would include cigarettes and cigar types other than premium cigars, which are used daily by 79.5% and 20.7–40.9% of their consumers, respectively, at Wave 3.[87]

When this study was presented in litigation, the Justice Department on behalf of the agency discounted its results. It noted that there is a non-trivial percentage of premium cigar consumers that smoke cigarettes (24.0% in the PATH Study's most recent wave), slightly exceeding the percentage of the entire population that smokes cigarettes (approximately 18.3%).[88] As a result, the Justice Department argued, it would be inappropriate to rely on the study's results for exclusive cigar consumers, because some premium cigar consumers are not exclusive cigar users; instead they use other tobacco products. But the PATH Study data demonstrates that the Justice Department's criticism is off point. Those premium cigar consumers who also smoke cigarettes, so-called dual users, use premium cigars less frequently than those who do not. The median dual user consumes premium cigars 0.7-1.1 days per

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[86] Indeed, only 36 out of 608 non-daily exclusive cigar consumers studied—that is, 6%—died of diseases sometimes associated with tobacco use between 1985 and 2011. *Id.* To generate even this small group, the study needed to track the health outcomes of 357,420 Americans over 26 years, a massive undertaking. *Id.* at E2.
[87] NERA Report at tbls.4a–c.
[88] NERA Report at tbl.2 and tbls.9a–c.

month.[89] Those dual users are not using premium cigars in a manner suggesting they are addicted to them, rather than to cigarettes, or that they are substituting premium cigars for cigarettes as a nicotine delivery system. The statistics regarding dual use demonstrate that cigarettes are the problem for those dual users, not premium cigars.

Epidemiologist Dr. Geoffrey Kabat independently has analyzed the results of the JAMA Study and of other studies that together represent the latest research on the association of cigar use with health outcomes. Dr. Kabat's report (the "Kabat Report," attached hereto as Exhibit 12) sets out his clear conclusion as to the import of those studies: Non-daily premium cigar smokers have no increased health risks compared to nonsmokers.[90] As nearly all premium cigar consumers use them less than daily, this is compelling evidence that premium cigars need not be subject to the same regulatory scheme as other tobacco products with far different use patterns and associated health concerns.

The question again becomes whether the costs of imposing this regulatory scheme on the premium cigar industry, including the shuttering of small businesses and the dramatic loss of jobs, is worth the benefits to the 0.0168% of American adults who use premium cigars daily and thus in a manner associated with negative health effects. To make this case, a regulator would have to show that its regulations will materially change the behavior of this small sliver of consumers. Every public policy expert would say that it is nearly impossible to use regulatory intervention to materially affect a number that is so low. And these regulations are very unlikely to affect the behavior of this small group. Premarket and substantial equivalence review will close businesses and drive premium cigar products off the market, but there will still be

[89] NERA Report at tbls.10a–c.
[90] Kabat Report at 5–6.

grandfathered premium cigars on the market for their use. And there is no evidence that there is an information gap to be corrected by large warnings. The usage pattern and epidemiological data show that the costs far outweigh any benefits from regulating premium cigars.[91]

2. *The Consumers of Premium Cigars Do Not Misperceive the Health Risks of Using Those Products*

The FDA grounded its decision to require the same health warnings for all cigars, including premium cigars, on a supposedly widespread misperception that cigars are "safe" alternatives to cigarettes. As an initial matter, if cigarette consumers truly believed that premium cigars were a safe alternative to cigarettes, we would expect them to increase their premium cigar use and decrease their cigarette use. That has not happened. Premium cigar consumers who also smoke cigarettes use premium cigars less frequently than the median premium cigar consumer. Indeed, premium cigar consumers carefully modulate their use of the product, in apparent recognition that frequent use may have negative health consequences. The new PATH data demonstrate that this misperception either does not exist or is not translating into consumer behavior, at least with regard to premium cigars.

In any event, the agency has never produced any valid data to show that premium cigar consumers perceive the product as a safe alternative to cigarettes. All the studies in question studied the perception of cigars in general, which do not have the demonstrated pattern of infrequent use that premium cigars do. Even taking those studies on their own terms, dealing with all cigars generally, it relied on stale or statistically insignificant data. Many of the studies

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[91] In fact, the new data cast such doubt on the FDA's original cost–benefit analysis that the agency must conduct a new, more detailed cost–benefit analysis to comply with Executive Orders 12,866 and 13,771. That analysis is all but certain to confirm that the costs are so great, and the benefits so small and speculative, that the deeming rule is a prime candidate for regulatory withdrawal pursuant to Executive Orders 13,771 and 13,777.

relied on data *predating* the implementation of a Federal Trade Commission ("FTC") warnings scheme in 2001, which required the seven largest mass-market cigar manufacturers to display health warnings on all of their cigar packaging and advertising.[92] Other studies were based on qualitative "focus group" discussions or on polls of concededly small and/or unrepresentative populations.[93] And yet other studies were no more than literature reviews, asserting in passing that the public at large misperceived the risks of cigar use based on the same handful of stale and ungeneralizable studies.[94]

More recent studies and data, including from the PATH Study and from the FDA's Health Information National Trends Survey ("HINTS"), refute the notion that the consumers of premium cigars harbor any misconceptions about the potential health hazards posed by those products. While very few studies address premium cigars as a distinct class of cigars, even studies that discuss cigars as an undifferentiated group confirm that the overwhelming majority of the public understands that cigar use can be dangerous. For example, according to research

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[92] *See* Reynolds Report app. B; *see also, e.g.*, 79 Fed. Reg. at 23,158 (citing Ref. 35, a 1999 report, and Ref. 116, a 2001 report discussing cigar risk perceptions in focus groups of urban African American youth, to claim that certain youth "had received very little cigar-specific health education, reinforcing the importance of alerting consumers about the dangers of smoking cigars"); *id.* at 23,159 (citing Ref. 123, a 2000 study regarding adolescent smokers' perception of health risks from *cigarettes*); *id.* at 23,168 (citing Ref. 28, a 1998 report, for the proposition that "FDA believes that a warning regarding [ ] potential health consequences is necessary because of consumers' widely held, but erroneous, belief that cigars are safe products if users do not inhale the smoke"); *id.* (citing Ref. 30, a 2000 report identifying cigar smokers' "optimistic bias" in estimates of their risk of developing cancer, in support of a claimed need for warnings to help smokers "better understand and internalize" potential and critical health consequences). Notably, Proposed Rule Ref. 35 specifically emphasized: "Most Of Our Teens Believe Smoking Cigars Is Bad For A Person's Health And That The Potential Harm Increases With More Frequent Use." PR Ref. 35 at 20. It goes on to state that 94% of teens report they believe smoking cigars is bad for a person's health. *Id.* This is a substantial number, and one entirely inconsistent with the FDA's stated concern.

[93] *See, e.g*, PR Ref. 158; FR Ref. 268/PR Ref. 118; FR Ref. 269.

[94] *See, e.g*, PR Ref 162; FR Ref. 35/PR Ref. 30; FR Ref. 270.

published last year in *Addictive Behaviors*, 98.2% of those surveyed in HINTS believed that all cigars are "harmful" and 72.8% agreed that all cigar use is "very harmful."[95]

The PATH data make it likely that percentage recognition of the health risks of cigars is even higher among premium cigar consumers. On average, premium cigar consumers have vastly higher levels of education than consumers of all other tobacco products. In Wave 1, 46.4% of premium cigar consumers aged 25 and older had completed college or beyond, several times the rate of users of non-premium traditional cigars (9.4%), cigarillos (10.6%), filtered cigars (9.2%), and cigarettes (12.0%).[96] By Wave 3, the share of premium cigar consumers with at least a college degree had climbed to 56.0%, compared to 16.5% of non-premium cigar users, 11.1% of cigarillo users, 4.9% of filtered cigar users, and 11.9% of cigarette users.[97] That compares with the 32.5% of American adults aged 25 and older who have a college degree.[98] Including individuals with at least an associate degree or some college education, the figure for premium cigar consumers in Wave 3 jumps to a staggering 87.8%, almost double the rate among filtered cigar users (38.6%) and cigarette users (44.8%) and substantially higher than the 58.9% of American adults age 25 and older with such education.[99]

Coupled with the marked disparity in income between consumers of premium cigars and consumers of all other tobacco products—45.4% of premium cigar consumers had household incomes exceeding $100,000 in Wave 3, more than three times the share of non-premium traditional cigar users (13.4%), and nearly six times the share of cigarette users (7.6%)—there is

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[95] Bernat et al., *supra* note 74, at 41 tbl.2.
[96] NERA Report at tbls.3a–c.
[97] NERA Report at tbls.3a–c.
[98] *See* Ryan & Bauman, *supra* note 38.
[99] *Id.*

simply no reason to believe that this cohort is ignorant of the health effects of cigar smoking.[100] Nor, for that matter, is there any basis for presuming that the well-resourced and well-educated consumers of premium cigars are incapable of making sophisticated decisions about the products they consume, much less that they need—or will be influenced by—massive health warnings.

3. *The Manufacturing, Marketing, Advertising, Labeling, and/or Packaging Restrictions in the FD&C Act and its Implementing Regulations Should Not Be Applied to Premium Cigars*

The FD&C Act *itself* imposes no restrictions on premium cigar manufacturing, marketing, advertising, labeling, or packaging. By its terms, the Act applies only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and sets forth a monolithic regulatory scheme designed specifically for those homogeneous, mass-produced goods.[101] It was only through the Deeming Rule that premium cigars became subject to *any* FDA regulation, and the FDA elected in that Rule to drop Congress's full regulatory scheme for cigarettes, unmodified, on those starkly different goods. And the agency went a step further to impose a special marketing standard requiring large warnings on all cigars, including premium cigars. While the agency concluded that the data available at the time (2014–2016) did not justify an exemption for premium cigars, the same simply cannot be said today. The most recent data and scientific studies provide hard proof that *premium cigars are made and used in ways that affect the public health differently than all other tobacco products*. Those differences fully justify exempting premium cigars from regulation.

a. The Premarket Review and Substantial Equivalence Scheme Makes No Sense for Premium Cigars

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[100] NERA Report at tbls.3a–c.
[101] *See* FD&C Act §§ 901–920, 21 U.S.C. §§ 387a–387t.

The biggest misfit of the FDA's regulation of premium cigars is the premarket review and substantial equivalence scheme. Congress enacted the TCA against a backdrop of legislative findings that cigarette companies had manipulated ingredients in their products to make them more addictive and had marketed cigarettes in a way that led consumers incorrectly to believe that some cigarettes were safer than others.[102] The cigarette industry was controlled by a handful of multi-billion-dollar companies, each with a few main product lines, so Congress required each cigarette and smokeless tobacco product to be reviewed and approved by the agency.[103] Importantly, however, the FDA applied this requirement only to new cigarette products, exempting any product marketed just two years before the Act's passage.[104]

The effects of this regulatory scheme are far more severe on premium cigars, even though the predominantly small business manufacturers of premium cigars are much less capable of bearing those burdens than international cigarette conglomerates. Rather than having only a few dozen main brands and only hundreds total like the cigarette industry, the premium cigar industry has intense variety and tens of thousands of separate products. This is a direct function of their manner of production: They are painstakingly made *by hand* and under the supervision of skilled artisans who select the best tobacco available to blend into a premium cigar satisfying the tastes of infrequent, but very discerning customers. As a result, a typical premium cigar manufacturer will have hundreds of offerings. For example, Ashton Cigars offers 665 unique SKUs, while Rocky Patel Premium Cigars offers 2,300 SKUs. Further, the four leading premium cigar manufacturers currently have more than 6,000 active SKUs for their premium

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[102] TCA § 2(38)–(39), (47)–(49), 123 Stat. at 1778-81.
[103] 21 U.S.C. § 387j(a).
[104] *Id.* § 387j(a)(1).

cigars, and the five online retailers examined in the Econsult Report each offered an average of approximately 10,000 unique premium cigar SKUs in 2017 alone.[105]

Overall, the premium cigar industry offers more than 20,000 separate products. But the costs of the review process rise in direct proportion to the number of products. On top of that, the existing scheme sweeps in all premium cigars introduced over the last eleven years, while only cigarettes newly brought to market in the *two years* prior to the initiation of regulation had to run the gambit. The result: A regulatory scheme that places more burdens and costs on a class of products that 0.48% of American adults consume barely once a month than on cigarettes, smoked by almost 34 million Americans every day.[106] And it is not just the costs on private business that are grossly out of proportion. FDA staff too will need to spend hundreds of hours reviewing each substantial equivalence or premarket review application from the premium cigar industry. And those are hours that could have been spent on addressing the real public health concerns posed by other tobacco products. The review process is not just wasteful and job killing, it is a dangerous distraction from real public health problems.

The costs of premium cigar substantial equivalence and premarket review having been established, the inquiry turns to what benefits the review process will achieve. The answer is few to none. Substantial equivalence review is entirely unnecessary for a premium cigar, because the proposed definition of premium cigars ensures that each will be made as cigars have been for centuries and will present no innovative or new issue of public health. Premium cigars are exactly the type of product that Congress wished to spare a drug-like premarket review process: It sought to preserve the tobacco products currently on the market and allow in

[105] Econsult Report at 21 & tbl.3.
[106] NERA Report at tbl.2 and tbls.4a–c.

nominally new products that shared core features with existing products.[107] If a cigar meets the proposed definition of a premium cigar, it will share eight core features with handmade cigars on the market in 2007—and 1907, for that matter. The cigars will be made by hand, from all natural tobacco, and *with no additives*. A premium cigar will never present the agency with the questions of how a novel artificial ingredient interacts with the tobacco or performs when combusted.[108] When it comes to premium cigars, the substantial equivalence process serves no purpose other than to drive premium cigar manufacturers out of business.

And the agency need not worry about new non-premium cigar products running for cover under the umbrella of premium cigars if they are exempted from regulation generally and the premarket review process in particular. The definition erects insuperable barriers to entry, including requirements that the products be made by hand and from expensive tobacco, such as long filler and natural wrappers. A non-premium cigar product simply cannot bear those costs and retain their customers. Non-premium cigar products rely on mechanization to deliver high-volume products at a palatable price; they simply cannot leap the fence into the premium cigar category.

It is worth noting that the substantial equivalence process, in its current form, is no answer to the disproportionate burdens of the regulatory scheme on premium cigars. In the initial stages of substantial equivalence review for cigars, the agency strayed far afield from the

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[107] *See* FD&C Act § 910(a)(3)(A), 21 U.S.C. § 387j(a)(3)(A) (defining a "substantially equivalent" tobacco product exempted from premarket review as a product that (i) "has the same characteristics as the predicate [i.e., pre-February 2007] tobacco product"; or (ii) "has different characteristics," but the information and/or data submitted to the FDA "demonstrates that it is not appropriate to regulate the product [through the premarket review process] because the product does not raise different questions of public health").

[108] Nor is there any history of product manipulation to make premium cigars more addictive that premarket review is needed to detect. Even if there had been, it would have been an abject failure, given the striking infrequency of use among premium cigar consumers.

statute, which would have regarded a cigar as "substantially equivalent" if it has the same "characteristics" (i.e., "materials, ingredients, design, composition, heating source, or other features") as a pre-February 2007 cigar.[109]

According to correspondence between one cigar manufacturer and the FDA regarding a substantial equivalence application for a premium cigar (redacted and attached hereto as Exhibit 13), the agency expects scientific testing and towering amounts of detailed data, regardless of expense or feasibility. The agency directed the company to respond with data about the product's "draw resistance," the mass of the tobacco filler, its density and moisture, and the porosity of the binder and wrapper.[110] These are data that cigar manufacturers have not traditionally compiled and that appear to require extremely sophisticated testing to determine. The agency also required the manufacturer to study how its product is used, including how many "puffs" (again undefined) a user might take off the cigar.[111] To the extent the length and width (gauge) of the cigar had changed, the agency wanted longitudinal studies about how those changes will not cause any greater incidence of disease.[112] Even though testing results for harmful and potentially harmful constituents ("HPHCs") are not due until 2019 and the agency has not published a rule specifying what will be required for cigars, the agency demanded HPHC testing results of both the applicant and the predicate cigars.[113] The agency sought extensive data about how they were stored and studies of how storage conditions may affect product

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[109] *Id.* § 387j(a)(3).
[110] *See* Ex. 13 at 2.
[111] *See id.* at 3.
[112] *See id.*
[113] *See id.* at 4-5.

stability.[114] The agency wanted ingredient listings *for the box in which they would be stored and the plastic wrappers in which they would be packaged*, because "[i]ngredients in cellophane are expected to differ from [those in a] wooden box."[115] Most incredibly, the FDA requested "ingredient and material information for cigar bands," that is, the slender pieces of paper that identify the cigar brand.[116]

All of this information must be provided not only for the premium cigar applying for approval, but also for the pre-2007 predicate product.[117] But, unlike for cigarettes, only predicate products from a decade ago can be used—forcing manufacturers to find the necessary information and data from, and *physically to test*, products from long ago. This will be an impossible task, as most such products likely have already been consumed. The agency's requirements also make it practically impossible to use another manufacturer's premium cigar as a predicate, because the agency requires detailed information about the manufacturing process for the predicate cigar—fermentation, aging methods and storage conditions—that will not be available to a competing manufacturer. And, again, given the qualities and use patterns of premium cigars, and the unique demographics of premium cigar consumers, there is no reason for running these products through a regulatory gauntlet designed in every way for cigarettes.

There is a simple and elegant solution for this profound mismatch: Exempt a class of premium cigars, as defined in this comment, from FDA regulation. Once the FDA confirms that a product has each of the defining features of a premium cigar, it necessarily follows that the

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[114] *See id.* at 5-6.
[115] *Id.* at 8 (emphasis added).
[116] *Id.*
[117] As if providing the information were not burden enough, the FDA instructed the manufacturer to "**submit all the information identified above so that it is <u>received</u> by us no later than 60 days from the date of this letter**." *Id.* at 9 (emphasis in original).

product is substantially equivalent to every other premium cigar and presents no different questions of public health. This approach is entirely consistent with the text of the TCA and with congressional intent, it presents no risks of migration or uptake in light of the demographics and use patterns of premium cigar consumers, and it avoids the counterintuitive result—long predicted by CRA and IPCPR—of driving truly premium products from the marketplace and consolidating cigar production in the hands of multi-national conglomerates.

b. Constituent Testing Is Inappropriate and Unnecessary for Premium Cigars, and Its Costs Would Drastically Outweigh Any Benefits

On top of the exhaustive scientific testing attendant to premarket and substantial equivalence review, the TCA further requires the manufacturers of covered tobacco products to test for and report to the FDA all "harmful or potentially harmful constituents" ("HPHCs") in their products.[118] As with premarket review, this scheme is a product of Congress' overriding concern with the history of alleged consumer deception and product manipulation in the cigarette and smokeless tobacco industries. None of these concerns is present in premium cigars. Moreover, even if the FDA were to insist on HPHC testing, no methodology currently exists to identify HPHCs in premium cigars. Mechanically applying the TCA's HPHC-testing mandate to premium cigars would destroy businesses and drive product consolidation, with no discernible public health benefit.

At the outset, HPHC testing makes absolutely no sense for premium cigars. As emphasized throughout this comment, premium cigars are handmade, with endless variations in construction, and contain only three natural ingredients: Tobacco leaf, water, and plant-based adhesive. Unlike cigarettes, smokeless tobacco, or e-liquids, premium cigars *by definition*

[118] 21 U.S.C. §§ 387d(a)(3), 387o(b)(1).

contain no synthetic chemicals or additives—the substances at the heart of the HPHC mandate. The agency has never expressed what results it hopes testing of such natural tobacco combustion will yield.

Even then, the manual construction of premium cigars, and the vast differentiation among brands and blends from box to box and year to year, make HPHC testing wholly ineffective. Whereas a single cigarette is indistinguishable from every other cigarette in a pack (or a production line for that brand), it is no exaggeration to say that *every* premium cigar is different. Weather, humidity, daily curing conditions, and the practice of each individual human cigar roller ensures this variation even within the same box of cigars. As such, running a single premium cigar through a battery of laboratory tests will convey little information about any other cigar, even one found in the same box.

To the extent the agency intends HPHC testing to reach nicotine delivery, its efforts are better directed at other tobacco products. Again, unlike cigarettes and smokeless tobacco, all reliable evidence indicates that premium cigars are not used in a manner consistent with feeding nicotine addiction. As explained in Section B, above, the PATH data reveal that nearly all premium cigar consumers (from 93.1% in Wave 1 to 96.5% in Wave 3) use premium cigars less frequently than daily.[119] By Wave 3, the median adult consumer of premium cigars used those products on only 1.3 days out of 30.[120] Likewise, the median dual user of premium cigars and cigarettes consumes premium cigars if anything less frequently than the median consumer of premium cigars—only 0.7–1.1 days per month, as compared to 1.5–1.9 days per month for

[119] NERA Report at tbls.4a–c; *see also* Corey et al., *supra* note 11, at 5 tbl.2; Kasza et al., *supra* note 33, at supp. app. tbl.S4.
[120] NERA Report at tbls.4a–c.

premium cigar users who are not current cigarette smokers.[121] And of those who also smoke cigarettes, only 4.4–5.3% consume premium cigars daily.[122] Simply put, these are not use patterns indicative of using premium cigars for nicotine delivery.

Even if there were some scientific basis for directing HPHC testing in premium cigars, the agency still would be confronted with a fundamental problem: No testing methodology currently exists for premium cigars. Existing methods, processes, and procedures for HPHC testing are designed for cigarettes and smokeless tobacco, not cigars. No equipment currently exists that is generally accepted for large cigar testing, to account for the inherent variability in cigars, the varied shapes and sizes of cigars, and the length of time it takes for a cigar to burn to completion.

Nor has the FDA issued promised guidance on HPHC testing *generally*. While the agency announced in 2016 that it intended to publish a regulation addressing the "requirements for the testing and reporting of tobacco product constituents, ingredients, and additives," its original deadline of April 2018 came and went,[123] and the regulation is conspicuously absent from the agency's current regulatory agenda.[124] The FDA cannot fairly demand that premium cigar manufacturers get ahead of the agency, much less the current state of science.

While the industry cannot accurately predict the costs of HPHC testing premium cigars, given the absence of appropriate technology and the lack of necessary guidance from the FDA,

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[121] NERA Report at tbls.10a–c.
[122] NERA Report at tbl.10a–c.
[123] *See View Rule: Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives (RIN 0910-AH59)*, Office of Info. & Regulatory Affairs, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201610&RIN=0910-AG59.
[124] *See Agency Rule List – Spring 2018: Department of Health and Human Services*, Office of Info & Regulatory Affairs, https://reginfo.gov/public/do/eAgendaMain.

the nature of the tests apparently contemplated by the industry make clear that the expenses will be considerable.[125] Coupled with the variety of premium cigars and the associated scope of testing, the costs of the HPHC mandate will devastate the premium cigar industry. Indeed, just as with premarket review, the costs will be directly proportional to the variety of premium cigars—and to no public health end. Far from advancing the agency's asserted interest in protecting the public from potentially dangerous products,[126] the result will be product consolidation and market exit, as only the manufacturers capable of bearing the costs of government regulation will survive. The premium cigars that have been made the same way for generations will be replaced by inexpensive, homogenized products that lack natural ingredients but are amenable to laboratory testing. And the small family businesses that populate the premium cigar industry and continue the tradition of handcrafting fine cigars from whole tobacco leaf will die out.

c. Health Warnings

Under current FDA regulations, all cigars, including premium cigars, must display one of the same six health warnings, on a rotating basis, on their packaging and advertisements.[127] The

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[125] *See* Ex. __ [SE Letter] at 4–5 (describing required HPHC testing). In fact, the agency itself declined to estimate the costs of HPHC testing in its original Regulatory Impact Analysis, as it expected to address that issue when it released the long-promised HPHC regulations. Office of the Comm'r, U.S. Food & Drug Admin., *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act: Final Regulatory Impact Analysis* 101–02 (2016) ("FRIA").

[126] *See, e.g.*, 81 Fed. Reg. at 29,020 (HPHC testing "will assist FDA in better understanding the contents of regulated products" and "in assessing potential health risks and determining if future regulations to address the health risks posed by particular products are warranted")

[127] 21 C.F.R. § 1143.5(a), (b).

warnings must cover 30% of the two principal display panels of every cigar box and 20% of every advertisement.[128] The warnings follow:

> (1) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale;
> (2) WARNING: Cigar smoking can cause lung cancer and heart disease;
> (3) WARNING: Cigars are not a safe alternative to cigarettes.
> (4) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers;
> (5) WARNING: Cigar use while pregnant can harm you and your baby.
> *Or* SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth, and Low Birth Weight; and
> (6) WARNING: This product contains nicotine. Nicotine is an addictive chemical.[129]

Premium cigars customarily are sold in ornate boxes with artistic designs and information on the tobacco's origins, vintage, varietal, aging process, limited editions, history of crafting and the company, and the qualities of the product. These boxes often are seen as collector's items in their own right and are treated as such, displayed on a mantle or used to store valuables long after the cigars are gone.

Through the combination of their blunt content and their sheer size and stark format, the warnings also convey a message about the risks of premium cigar use that is incomplete and misleading in light of current science and how consumers actually use premium cigars. To reiterate, a recent *JAMA* paper concluded that using premium cigars—with the frequency with which they are used by 96.5% of premium cigar consumers—does not lead to any statistically significant increase in mortality.[130] Dr. Kabat's analysis further demonstrates that typical premium cigar users do not face increased health risks compared to nonsmokers, let alone

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[128] *Id.*
[129] *Id.*; *see, e.g.*, Decision and Order at 3–9, *In the Matter of Consol. Cigar Corp.*, Docket No. C-3966 (F.T.C. Aug. 25, 2000) (detailing substance and format requirements for FTC warnings).
[130] *See* Christensen et al., *supra* at note 81, at E1, E6 tbl.3.

comparable health risks to those of typical cigarette smokers.[131] Such clarifying context is missing from the health warnings that current FDA regulations mandate be affixed to the packages of premium cigars and all advertising about them. The warnings do not say, for example, that "*if used frequently or in combination with other tobacco products*," premium cigars "can cause lung cancer and heart disease" or "cancers of the mount and throat."[132] Indeed, the unconditional warning that "Tobacco smoke increases the risk of lung cancer and heart disease" fails even to include a rudimentary qualifier like "can" or "may."[133]

Several other of the required warnings are further disconnected from how actual consumers use premium cigars. For example, the warning that "Cigar use while pregnant can harm you and your baby" overlooks that only 1.5–3.5% of premium cigar consumers are women, and there is no evidence that any of those used the product while pregnant. [134] Nor is there any significant basis for concern that consumers substitute premium cigars for cigarettes as an alternative means of nicotine delivery, as there is with regard to small cigars or cigarillos.[135] After all, even those premium cigar consumers who also smoke cigarettes do not use premium cigars with greater frequency, the median dual user consuming premium cigars 0.7-1.1 days per month.[136] Yet the concern that cigarette consumers are turning to premium cigars as an alternative nicotine delivery system is the only apparent justification for the warning, "Cigars are not a safe alternative to cigarettes."[137] Likewise, the blunt warning that "Nicotine is an addictive

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[131] *See* Kabat Report at 5–6.
[132] 21 C.F.R. § 1143.5(a)(1).
[133] 21 C.F.R. § 1143.5(a)(1).
[134] 21 C.F.R. § 1143.5(a)(1); NERA Report at tbls.3a–c.
[135] 21 C.F.R. § 1143.5(a)(1); NERA Report at tbls.4a–4c, 10a–c.
[136] NERA Report at tbls.10a–c.
[137] 21 C.F.R. § 1143.5(a)(1).

chemical" is misplaced as applied to premium cigars, given that premium cigars are used sporadically rather than with a frequency consistent with nicotine addiction.[138]

Further, there is no basis to conclude health warnings would have a meaningful effect on premium cigar initiation and use.[139] Instead, a 2018 report analyzing the PATH data found that, even when premium and mass-marketed cigar types were combined, receptivity to cigar advertising is the lowest among all forms of tobacco advertising, regardless of the age group studied.[140] Warnings further would have no meaningful effect on initiation or use because consumers of premium cigars already understand the potential risks of the product. As explained in greater detail in the Reynolds Report, even without any warnings, there is no evidence that the general population misunderstands the health effects of cigars.[141] Moreover, premium cigars are luxury goods that are used by adults with higher education levels, on average, than users of other tobacco products, further indicating that warnings will have little effect on the target audience. Plainly, there is no basis to conclude that adding warnings containing information consumers already believe will have any appreciable effect on initiation or use.

Warnings also will have no meaningful effect on youth premium cigar initiation and use. As discussed previously, underage use of premium cigars is already so low that it is even difficult to reliably measure.[142] Instead of advertising and marketing, the relevant literature has reported that underage risky behaviors, such as tobacco use, are typically a result of personal,

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[138] 21 C.F.R. § 1143.5(a)(1); NERA Report at tbls.4a–c (median consumer of premium cigars uses them on just 1.3-1.7 days out of 30).
[139] Reynolds Report at 13.
[140] Pierce et al., *Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study*, JAMA Pediatrics at 447 (2018) (attached hereto as Exhibit 14).
[141] Reynolds Report at 16.
[142] Reynolds Report at 4.

social, and environmental factors.[143] These risk factors include tobacco use by peers, other family members, and significant others, as well as personality factors, which are all consistently and highly correlated with underage tobacco use.

Studies and evidence do not suggest that the proposed changes to the warnings mandated by the FDA will be more effective in preventing underage smoking initiation via premium cigar use or will contribute to cessation efforts by youth who already use premium cigars.[144] Instead, two studies have found that youths are less receptive to cigar advertising than to any other form of tobacco advertising,[145] suggesting that they will be similarly unreceptive to premium cigar warning labels. Regardless, premium cigars are generally sold in specialty cigar shops closed to the underaged or by age-verified mail order houses. Thus, the exposure rates of such labeling and any required warnings to underage persons would simply be too low to have any hope of being effective in either product promotion or health education among this group. Consequently, exposure to premium cigar labeling, advertising, and marketing is highly unlikely to have any appreciable effect on underage premium cigar use, which already is statistically indistinguishable from zero. In view of the foregoing, it is evident that the existing FDA warnings are inappropriate for premium cigars, both in format and in substance.

4. *Exempting Premium Cigars From Regulation Would Advance the Agency's Obligation to Carry Out the President's Deregulatory Program*

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[143] Reynolds Report at 5, 12.
[144] Reynolds Report at 13, 15.
[145] Pierce et al., *Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study*, JAMA Pediatrics at 447 (2018); Pierce et al., *Receptivity to Tobacco Advertising and Susceptibility to Tobacco Products*, Pediatrics (2017) (attached hereto as Exhibit 15).

The exorbitant and wide-ranging costs of regulating premium cigars would far exceed any associated public health benefits. Exempting premium cigars from regulation would carry out the President's unambiguous instructions to federal agencies to engage in rigorous cost–benefit analysis and eliminate regulations failing that test.[146] Indeed, the Administration has unequivocally instructed agencies to "assess and consider both the benefits and costs of regulatory actions, including deregulatory actions, when making regulatory decisions, and issue regulations *only upon a reasoned determination that benefits justify costs*."[147] And, consistent with that objective, the President issued Executive Order 13771, barring departments and agencies from promulgating regulation of business without pulling down two regulations and requiring them to eliminate regulatory costs of $1 on the business community for every $1 in additional costs that a new regulation would impose.[148]

The premium cigar industry is populated by small businesses, often family enterprises that have practiced the craft for generations. The products, in fact, look much the same as they did centuries ago, consist of the same essential ingredients, and are made the same way. Premium cigars are used overwhelmingly by older, better-resourced, and better-educated adults who have full knowledge of the potential risks to their health from overuse. Premium cigars are used not for nicotine delivery but for an occasional indulgence. And running premium cigars through a

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[146] *See* Executive Order 13,771 § 1 (Jan. 30, 2017) ("It is the purpose of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources. In addition to the management of direct expenditure of taxpayer dollars through the budgeting process, it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."); Executive Order 13,777 § 3(d)(iii) (Feb. 24, 2017) (directing Regulatory Reform Task Forces to evaluate and identify regulations that "impose costs that exceed benefits").
[147] Guidance Implementing Executive Order 13,771 (Apr. 5, 2017) (emphasis added).
[148] *See* Executive Order 13,771 § 2(c).

regulatory gauntlet self-evidently designed for identical, mass-produced, synthetic goods produced by billion-dollar corporations will impose literally existential costs on premium cigar manufacturers. The FDA predicted as much when it issued the deeming rule: It acknowledged that 90% of the entities affected by the deeming rule were small businesses, up to half of the handmade cigars currently available could be forced out of the market, and the estimated costs to small cigar manufacturers or importers would be between $277,750 and $397,350 upfront and no less than $235,060 annually thereafter, culminating in its blunt observation that "some firms may exit the market."[149] Industry estimates place the cost of regulation even higher. It is little surprise, then, that when the FDA proposed the deeming rule in 2014, the federal Small Business Administration's Office of Advocacy admonished the agency for failing to adequately examine the effect of the rule on small businesses and neglecting to give serious consideration to less burdensome regulatory alternatives.[150] Meanwhile, the new data above and experience since the inception of regulations confirm that these costs are not outweighed by benefits to the public health. In sum, not only would the costs of regulation dramatically outweigh any benefits, but costs of that magnitude could not easily be recouped by the agency.

By contrast, if the agency were to reverse its previous decision to treat all cigars as homogeneous products and instead exempt premium cigars from FDA regulation, it would then have a significant deregulatory credit to apply towards another regulation of business on a topic

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[149] Office of the Comm'r, U.S. Food & Drug Admin., *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act: Final Regulatory Impact Analysis* 22, 78–80, 132, 133 (2016).

[150] Comment from SBA Office of Advocacy at 3–6, ID No. FDA-2014-N-0189-43271 (June 11, 2014), *available at* https://www.regulations.gov/document?D=FDA-2014-N-0189-43271.

of its choosing.[151] This deregulatory credit can be applied to offset a new FDA regulatory action, or a regulatory action issued by a different component within HHS.[152] These are important considerations for the agency, over and above adherence to the Administration's deregulatory program.

That program, by all accounts, is paying dividends. By the end of the President's first year in office, the Administration had cut regulatory costs by $8.1 billion and has repealed, withdrawn, or delayed hundreds of unnecessary and burdensome regulations that made it more difficult for hard-working Americans to make a living and that had been smothering the Nation's economy. This slowdown and reversal of previous Administrations' regulatory activity is a welcome relief to American small businesses and the U.S. economy as a whole. Since announcing the Administration's regulation rollback, the economy has added nearly 3 million jobs, unemployment levels have plummeted to their lowest level in 18 years, and the Dow Jones Industrial Average broke above 25,000 for the first time in history due to strong jobs data. The agency should not impede that growth by rubberstamping an ill-conceived regulation issued by the last Administration—precisely the kind of job-killing, overbearing government action this President vowed to end.

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CRA and IPCPR are grateful for the opportunity to provide data and evidence regarding the appropriate regulatory treatment of premium cigars. We urge the FDA to exempt a category of premium cigars, as defined in Part A of this comment, from the FDA's regulatory scheme. We are available at the agency's convenience to answer any questions.

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[151] Executive Order 13771 § 1; Guidance on Implementing Executive Order 13771, at 2, 13.
[152] Guidance on Implementing Executive Order 13771, at 3, 13.

Sincerely,

/s/ Michael J. Edney

Michael J. Edney