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# The Public Health, Financial and Employment Impacts of Excluding Handmade Cigars from Coverage by FDA's Final Rule

## ECONOMIC INFORMATION FOR FDA'S CENTER FOR TOBACCO PRODUCTS IMPLEMENTATION OF EXECUTIVE ORDERS 13771 AND 13777

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# Introduction

The U.S. Food and Drug Administration (FDA) has requested comments and information to help it identify regulations that can be modified, repealed, or replaced to achieve meaningful reduction of regulatory burdens while achieving FDA's public health mission and fulfilling its statutory obligations. The agency's Regulatory Reform Task Force must attempt to identify regulations that, among other things:

- eliminate jobs, or inhibit job creation or
- impose costs that exceed benefits.

This report shows that the FDA's Final Rule deeming handmade cigars subject to Chapter IX of the Food, Drug, and Cosmetic Act is a regulation that is certain to eliminate jobs and impose substantial costs that exceed any benefits of the rule.[1]

The agency also asked that comments address several questions. This report addresses two such questions:

1. Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.

2. Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection? If yes, provide examples of alternatives that may reduce costs to industry while retaining the same level of public health protection.

The answer to each of these questions is "yes." As detailed in the rest of this report:

1. Yes, compliance with the regulation will be so difficult and costly that it threatens to put almost all U.S. handmade cigar manufacturers and importers out of business. *Using FDA's own cost estimates*, the regulation likely will cause 85 to 90 percent of domestic cigar manufacturers and importers (320-338 small businesses) to go out of business, leading to the loss of over 3,500 U.S. manufacturing jobs and almost 1,800 jobs at U.S. importers. Because handmade cigars have the highest cost of compliance per cigar, almost all of the cigar manufacturers and importers that go out of business because of this rule will be manufacturers and importers of handmade cigars. The expected reduction in the number of handmade cigars on the market due to the rule is also likely to cause the closure of at least 494 tobacco retailers and the loss of as many as 19,800 U.S. retail jobs.

2. Yes, FDA could achieve the goal of the regulation ("to reduce death and disease from tobacco products"[2]) and the same level of public health protection by excluding handmade cigars from

[1] Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) ("Final Rule").
[2] 81 Fed. Reg. 28975 (May 10, 2016).

the Final Rule and allocate the $198 million (discounted at 3%) of regulatory cost savings to apply against other FDA regulations that could improve public health.

## Discussion of FDA's Estimates of Costs for Handmade Cigar Manufacturers and Importers and Updates to FDA's Estimates

For this report on the business and job consequences of FDA's Final Rule for the cigar industry, we will use FDA's estimates of costs for the rule. Tables 1 and 2 show FDA's estimates for the number and size of U.S. cigar manufacturers and importers covered by the Final Rule. The tables also show more recent data obtained for this report to update FDA's cost estimates.

Table 1. Number and Characteristics of U.S. Cigar Manufacturers

| | FDA | This Report |
|---|---|---|
| Domestic Cigar Manufacturing Establishments | 113[3] | 160[4] |
| Percentage of Domestic Tobacco Manufacturing Establishments per Employee Size Category | 0-4 employees: 37%[5]<br>5-9 employees: 9%<br>10-19 employees: 5%<br>20-99 employees: 29%<br>100-499 employees: 10%<br>500+ employees: 11% | 1-4 employees: 44%[6]<br>5-9 employees: 9%<br>10-19 employees: 8%<br>20-99 employees: 21%<br>100-499 employees: 15%<br>500-999 employees: 2%<br>1,000+ employees: 2% |
| Portion of Tobacco Manufacturers that Meet SBA's Definition of Small | 89%[7] | 98+%[8] |

[3] FDA, Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis ("FRIA"), Table 4. Available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf
[4] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.
[5] FRIA, Table 41.
[6] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.
[7] FRIA, Table 40.
[8] Percent of establishments with fewer than 1,500 employees based on U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.

Table 2. Number and Characteristics of U.S. Cigar Importers

| | FDA | This Report |
|---|---|---|
| Domestic Cigar Importing Establishments[9] | 216 | 216 |
| Percentage of Domestic Tobacco Importing Firms per Employee Size Category | 0-4 employees: 45%[10]<br>5-9 employees: 18%<br>10-19 employees: 13%<br>20-99 employees: 15%<br>100-499 employees: 6%<br>500+ employees: 2% | 1-4 employees: 47%[11]<br>5-9 employees: 15%<br>10-19 employees: 13%<br>20-99 employees: 17%<br>100-249 employees: 5%<br>250+ employees: 3% |
| Portion of Tobacco Importers that Meet SBA's Definition of Small | 92%[12] | 97%[13] |

FDA estimated that there are 113 domestic cigar manufacturers and 216 cigar importers based on 2013 data from the Alcohol and Tobacco Tax and Trade Bureau. Data from the 2015 U.S. Census Bureau, County Business Patterns indicate that there are 160 domestic cigar manufacturers, an increase of 42 percent in two years. The Census data on tobacco importers is not granular enough to provide a more up to date estimate of the number of cigar importers. We therefore use FDA's estimate in this report, so that the total number of domestic cigar manufacturers and importers is 376 (an increase of 14 percent over the estimate that FDA made using 2013 data). However, if the number of cigar importers has increased since 2013 at a rate similar to that of domestic cigar manufacturers, then the impact of the rule on the cigar import sector (i.e., the sector relevant to handmade cigars) is underestimated here.

The U.S. Small Business Administration (SBA) defines a "small" tobacco manufacturer as one that has fewer than 1,500 employees and a "small" tobacco importer as one that has fewer than 250 employees.[14] FDA used 2007 Census data to estimate the percentages of cigar manufacturers (89%) and cigar importers (92%) that meet SBA's definition of a small tobacco manufacturer or importer. However, the 2007 Economic Census aggregated into one category all firms with 500 or more employees. This led FDA to underestimate the number of tobacco manufacturers and importers that SBA would classify as "small." The 2015 Census data is more disaggregated and separates firms with 500 to 999 employees from those with 1,000 or more employees. Using the 2015 U.S. Census Bureau County Business Patterns data, we can say that 98 percent or more tobacco manufacturers meet SBA's definition of a small business (1,500 tobacco manufacturing employees) because 98 percent of tobacco manufacturing firms

[9] FRIA, Table 4.
[10] FRIA, Table 41.
[11] U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[12] FRIA, Table 40.
[13] Percent of establishments with fewer than 250 employees based on U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[14] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, 2016, p 8.

have fewer than 1,000 employees. Using the more up to date data also shows that 97 percent of tobacco importers have fewer than 250 employees.

Table 3 shows the cost of making handmade cigars subject to FDA regulation. FDA's Final Regulatory Impact Analysis reports the present value of the costs for cigar manufacturers and importers. However, it does not specifically report the present value of costs for handmade cigar manufacturers and importers. FDA's Preliminary Regulatory Impact Analysis, however, shows that handmade cigar manufacturers and importers account for 86 percent of the cost for all cigar manufacturers and importers.[15] Adjusting the present value of the costs for handmade cigar manufacturers and importers to account for the higher number of current domestic cigar manufacturers increases the costs by 14 percent to $197.8 million (discounted at 3%) or $156.9 million (discounted at 7%). If FDA exempts handmade cigars from the Final Rule, that is the amount that FDA could apply under Executive Order 13771 toward other rulemakings that could promote and protect public health.

Table 3. Cost of Covering Handmade Cigars

| | FDA | This Report |
|---|---|---|
| Present Value of Costs for Cigar Manufacturers and Importers[16] | Discounted @ 3%: $201,800,000<br>Discounted @ 7%: $160,000,000 | |
| Handmade Cigar Portion of Total Cigar Costs[17] | 86% | |
| Present Value of Costs for Handmade Cigar Manufacturers and Importers | Discounted @ 3%: $173,500,000[18]<br>Discounted @ 7%: $137,600,000 | Discounted @ 3%: $197,800,000[19]<br>Discounted @ 7%: $156,900,000 |

## Handmade Cigar Manufacturers and Importers Forced to Close

The Final Rule imposes very large costs on cigar manufacturers and importers. In response to a comment by one cigar trade association, FDA states, "we acknowledge in our analyses of the proposed and final rules that small entities may be adversely affected, and many may exit."[20] However, FDA never attempts to estimate the number of cigar manufacturers or importers that will be forced to shut down as a result of the rule.[21] The data to make reasonable estimates of cigar industry closure exist, and we use them in this report to reveal the business implications of the rule.

[15] FDA, Preliminary Regulatory Impact Analysis ("PRIA"), Table 35.
[16] FRIA, Table 32.
[17] PRIA, Table 35, ($115.6 + $224.2) ÷ ($115.6 + $224.2 + $53.8) = 0.86.
[18] 86% of $201.8 million and $160 million.
[19] 142% of $173.5 million and $137.6 million to adjust for the additional manufacturers.
[20] FRIA, p 47.
[21] In response to comments on the effect of the rule on business closure and products removed from the market, FDA refers to a section of the FRIA with the heading, "Costs of Market Adjustments." The section merely contains vague language about potential effects of the rule on business operations and products offered. FDA offers no attempt at quantification of the effects of the rule on business closure, jobs lost, or products withdrawn from the market. FDA does not even offer qualitative, relative indications of the size of the effects (e.g., small, large, significant, etc.). See FRIA, p 104.

To put the costs that FDA estimated for cigar manufacturers and importers into a context relevant for business, we obtained data on annual sales revenues for domestic cigar manufacturers and tobacco industry net profit margins. We do not have data on cigar manufacturing or importing net profit margin. As a proxy, we use CSIMarket data on net profit margins for publicly-traded tobacco product manufacturers. In the third quarter of 2017, the 14 publicly-traded tobacco product manufacturers reported a net profit margin of 22 percent on an annual basis. Applying this net profit margin to November 2017 data from Dun & Bradstreet on annual sales revenue for certain U.S. cigar manufacturers strongly suggests that FDA's estimates of the costs of the rule for cigar manufacturers and importers will exceed the total profit of the vast majority of domestic cigar manufacturers and importers.

Table 4 shows FDA's cost estimates and the data used to put the cost of the rule in context.

Table 4. Impact of the Rule on Cigar Industry Profitability

| | FDA | This Report |
|---|---|---|
| Cost per Small Cigar Manufacturer or Importer[22] | Year 1: $277,750 - $397,350<br>Year 2: $291,760 - $411,290<br>Year 3+: $235,060 - $256,960 | |
| Annual Revenue for Cigar Manufacturers[23] | | Minimum: $48,720<br>Median: $252,580<br>Maximum: $64,780,440 |
| Net Profit Margin for Publicly-Traded Tobacco Companies[24] | | 22% |
| Annual Net Profit for Cigar Manufacturers[25] | | Minimum: $10,720<br>Median: $55,570<br>Maximum: $14,251,700 |
| Percent of Cigar Manufacturers or Importers for whom FDA Compliance Cost Estimates Exceed Net Profits[26] | | Years 1 & 2: 87% - 89%<br>Year 3+: 85% |

FDA estimates that the year 1 cost of compliance for a small cigar manufacturer or importer will range between $277,750 and $397,350. Costs in year 2 increase to between $291,760 and $411,290. Then in the third and following years costs decrease and remain stable at a range of $235,060 and $256,960. Assuming that FDA's estimates are accurate, then the Dun & Bradstreet and CSIMarket data indicate that half of the cigar manufacturers in the U.S. have annual profits that are one-fifth of the lowest-

[22] FRIA, Table 42.
[23] Dun & Bradstreet, SIC Code 21210000 (specific for cigars).
[24] CSIMarket.com data for the tobacco industry reported for Q3 2017 and the trailing 12 months. https://csimarket.com/Industry/industry_Profitability_Ratios.php?ind=508
[25] Annual revenue amounts multiplied by 22% net profit margin factor.
[26] Calculated using data from Dun & Bradstreet, SIC Code 21210000 (specific for cigars).

bound cost of compliance with the rule. In fact, the lowest-bound cost of compliance with the rule exceeds the total sales revenue of half of the domestic cigar manufacturers.

Applying the net profit margin factor to the annual sales revenue data for each of the businesses in the Dun & Bradstreet database indicates that FDA's first and second year compliance cost estimates exceed the total profit of 87 to 89 percent of U.S. cigar manufacturers. And even if the businesses find some way to fund the initial start-up costs of the rule, the ongoing annual costs of the rule will exceed the annual profits of 85 percent of U.S. cigar manufacturers. The costs of the rule will make 85 to 90 percent of domestic cigar manufacturers unprofitable. Under these circumstances, it is almost certain that the rule will force 88 percent of U.S. cigar manufacturers out of business.

It is also important to consider that handmade cigar manufacturers are the smallest of U.S. cigar manufacturers with lower annual revenues and profits than U.S. machine-made cigar manufacturers. Therefore, it is very likely that the 85 percent of cigar manufacturers that the rule will cause to close are handmade cigar manufacturers.

FDA estimates that the costs of the rule for cigar manufacturers and importers are the same. 27 Dun & Bradstreet does not have data granular enough to estimate cigar importer annual revenues. CSIMarket data for the wholesale industry (of which cigar importers are a part) indicate that net profit margins are extremely low – about 2 percent for the year ending in the third quarter of 2017. The very low profit margins mean that even small increases in costs pose serious threats to the viability of the business if cost increases are not passed on as FDA asserts. Even without more information, we believe that it is very reasonable to use the impact of the rule on cigar manufacturer profitability as a proxy for the impact of the rule on cigar importer profitability. Therefore, we estimate the rule to make 88 percent of cigar importers so unprofitable that they cease operation.

## Jobs Lost in U.S. Cigar Manufacturing and Importing

The closure of U.S. cigar manufacturers and importers will put thousands of employees out of work. Tables 5 and 6 show the breakdown of the percentage of cigar manufacturing or importing facilities and cigar manufacturing or importing employees by the employee-size category of the establishment. If we assume that the establishments with the fewest employees are those that will be forced out of business by the rule, then we can estimate the number of U.S. manufacturing and importing jobs that will be lost because of the rule.

Eighty-two percent of U.S. cigar manufacturers have fewer than 100 employees. We estimate that all 2,071 employees at those manufacturing establishments will lose their jobs as a result of the rule. The 2015 Census Bureau County Business Patterns reports 17 manufacturing establishments with 100 to 249 employees. As a group, those 17 establishments employ 2,543 people, or 150 people per establishment.

[27] FRIA, Table 42.

Adding the employee equivalent of 9.6 additional establishments (1,440 employees) to the 2,071 employees in establishments with fewer than 100 employees brings the total manufacturing jobs lost equivalent to 88 percent of manufacturing establishments that have profits that are less than the start-up costs of the rule. Therefore, we estimate that the rule causes the loss of 3,511 U.S. manufacturing jobs.

Table 5. 2015 U.S. Census Data on the Size Distribution on Manufacturers and Employees

| | Percentage of Manufacturers (out of 160 total U.S. cigar manufacturing establishments) | Number of Employees (out of 13,872 total U.S. cigar manufacturing employees) |
|---|---|---|
| Percentage of Domestic Tobacco Manufacturing Establishments and Employees per Employee Size Category[28] | 1-4 employees: 44%<br>5-9 employees: 9%<br>10-19 employees: 8%<br>20-99 employees: 21%<br>100-249 employees: 11%<br>250-499 employees: 4%<br>500-999 employees: 2%<br>1,000+ employees: 2% | 1-4 employees: 93<br>5-9 employees: 97<br>10-19 employees: 159<br>20-99 employees: 1,722<br>100-249 employees: 2,543<br>250-499 employees: 2,466<br>500-999 employees: 2,260<br>1,000+ employees: 4,532 |

86 percent of cigar importers have fewer than 50 employees. We estimate that all 1,450 employees at those importing establishments will lose their jobs as a result of the rule. To go from 86 percent of the 216 cigar importing establishments to 88 percent (the percent of importers with FDA-estimated costs of the rule exceeding profits), we need to add 2 percentage points from the 50-99 employee size category. Since 6 percent of the total number of cigar importers are in that category, that additional portion needed is one-third of the employees from that size category – 332 employees. So adding 332 employees to the 1,450 employees in establishments with fewer than 50 employees brings the total importing jobs lost equivalent to 88 percent of importing establishments that have profits that are less than the start-up costs of the rule. Therefore, we estimate that the rule causes the loss of 1,782 U.S. importing jobs.

[28] U.S. Census Bureau, County Business Patterns, 2015, NAICS 312230.

Table 6. 2015 U.S. Census Data on the Size Distribution on Importers and Employees

| | Percentage of Importers (for 216 U.S. cigar importing establishments out of 1,485 total tobacco importing establishments) | Number of Employees (for 7,382 U.S. cigar importers out of 50,753 total tobacco importing employees) |
|---|---|---|
| Percentage of Tobacco Importing Establishments and Employees per Employee Size Category[29] | 1-4 employees: 47%<br>5-9 employees: 15%<br>10-19 employees: 13%<br>20-49 employees: 11%<br>50-99 employees: 6%<br>100-249 employees: 5%<br>250+ employees: 3% | 1-4 employees: 161<br>5-9 employees: 213<br>10-19 employees: 363<br>20-49 employees: 713<br>50-99 employees: 997<br>100-249 employees: 1,628<br>250+ employees: 3,307 |

Therefore, the FDA-estimated costs of the Final Rule imply that 88 percent of U.S. cigar manufacturers and importers (331 establishments) will become unprofitable because of the rule and have to close, resulting in the loss of 5,300 U.S. jobs.

## Closure of Tobacco Retailers

The rule imposes onerous costs on cigar manufacturers and importers. By FDA's own estimates, at a minimum, each small cigar manufacturer and importer will have to pay over one-quarter of a million dollars a year to comply with the rule. And according to FDA, even costs in the out years could still be that high on an annual basis.[30]

Built into FDA's cost estimates in its Preliminary Regulatory Impact Analysis was the expectation that 10 percent to 50 percent of cigar UPCs (also referred to as SKUs or product/package combinations) would no longer be offered for sale because the costs of the rule would make producing them unprofitable.[31] In its Final Regulatory Impact Analysis, FDA changed its estimate of the percentage of cigar products that would no longer be offered as a result of the rule to 5 percent, without offering any justification or explanation for such a dramatic change.[32]

Nevertheless, we can use FDA's estimates of product reduction to estimate the effect of the rule on tobacco retailers, almost all of which sell handmade cigars. According to the U.S. Census Bureau County Business Patterns, in 2015 there were 11,140 tobacco retailers in the U.S., including many of which

[29] U.S. Census Bureau, County Business Patterns, 2015, NAICS 424940.
[30] FRIA, Table 42.
[31] PRIA, pp. 26, 29, and 60.
[32] FRIA, p 47.

specialize in selling handmade cigars.[33] In order to stay in business, specialty cigar stores depend on being able to offer a very large selection of handmade cigars, a selection of new product additions, a special selection of rare handmade cigars (or even boutique cigars that are unique to a single store), and store personnel with extensive knowledge and experience with handmade cigars in order to assist customers in selecting new brands, product lines, varieties and sizes. Handmade cigar smokers ("cigar aficionados" as they are often referred to) are similar to wine and distilled spirits connoisseurs, craft brew drinkers, people who fish with flies, or "foodies." Consumption of the product is part avocation. Searching for, learning about, and trying new and unique items is part of the attraction of the purchase. Specialty cigar retailers are highly dependent on a wide offering of products. The fewer products and the fewer new products there are available for customers, the less valuable are knowledgeable and experienced sales staff. And the fewer products available for purchase in the category, the fewer tobacco retailers the market will support.

The 2015 County Business Patterns reports a total of 11,140 tobacco stores in the U.S. employing a total of 42,106 people, or about 4 employees per store on average. We assume that a reduction in product variety causes a proportional decrease in the number of stores.

Table 7 shows the number of tobacco stores estimated to close using this method.

Table 7. Estimates of Tobacco Retail Store Closure and Jobs Lost

| | 5% Fewer SKUs | 10% Fewer SKUs | 50% Fewer SKUs |
|---|---|---|---|
| Tobacco Stores Closed | 494 | 989 | 4,944 |
| Tobacco Store Jobs Lost | 1,976 | 3,956 | 19,776 |

We provide estimates for all three of the percentages of product reduction that FDA has used during the rulemaking. We include the higher estimates from the Preliminary Regulatory Impact Analysis because FDA offered no rational basis for the dramatic reduction that it adopted in the Final Regulatory Impact Analysis. Moreover, considering that almost 90 percent of U.S. cigar manufacturers and importers will be forced to close because the rule will make it unprofitable for them to operate, the higher estimates of SKUs lost because of the rulemaking seem to be the most reasonable.

## Financial Stress on Small, Family Farms

FDA's Final Regulatory Impact Analysis gives a brief mention to the effect of implementation of the Final Rule on tobacco farms in the United States. FDA refers to data from the U.S. Department of Agriculture that one percent of tobacco production was for use in cigars. The agency then states that once the Final Rule goes into effect tobacco farmers may switch to farming other crops. FDA fails to acknowledge that farms that grow tobacco, and especially cigar tobacco, will have difficulty switching to other crops

[33] U.S. Census Bureau, County Business Patterns, 2015, NAICS 453991.

without a loss of income. Tobacco for cigars is a high value crop, and it is usually difficult for farmers to switch to other high value crops. The farms that grow tobacco for handmade cigars are small, family farms like the Jepson Family Farm Partnership growing in Simpson County, Kentucky and Robertson County, Tennessee.[34] Jepson Farms quit growing burley tobacco used in cigarettes several years ago to grow 150 acres of dark tobacco used in cigars.[35] Growing tobacco for cigars has been instrumental in keeping the Daughter's & Ryan farm in St. James Parrish, Louisiana operating.[36] In Lake County, Florida, a small, start-up, Florida Sun Grown Farm grows premium tobacco exclusively for cigars.[37] In Lancaster County, Pennsylvania, almost 1,000 Amish family farms grow tobacco, some of it as wrappers for cigars.[38] The income from tobacco is important to keeping the farms in business.[39] In the Connecticut River Valley, many small, family tobacco farms have been under significant financial pressure for years. The key to staying in business, they say, is growing shade tobacco that is used for premium cigar wrappers.[40] Farmers in Connecticut rotate the crops of shade tobacco with high-end broadleaf tobacco, both of which are used in handmade cigars.[41] So small, family farms that supply tobacco for handmade cigars from Florida to New England will be negatively impacted by the Final Rule. FDA failed to respond in any meaningful way to the concerns about the impacts on tobacco growers raised in comments, even though comments were offered on the effect of the rule on agriculture.[42] Moreover, although there are hundreds of small tobacco farms, and the Final Rule will certainly impose a significant economic impact on a substantial number of small entities (as addressed by the Regulatory Flexibility Act), FDA did not even make mention of small tobacco farms on its Small Entity Analysis as required by the Regulatory Flexibility Act.[43]

## Additional Costs and Negative Impacts of the Rule

The estimates of business closures and jobs lost in this report are based on FDA's own estimates of the cost of compliance with the Final Rule. In numerous comments and submissions to FDA, the handmade cigar industry has disputed FDA's cost estimates and provided FDA with justification for higher cost estimates. If FDA accepts those higher cost estimates and eliminates handmade cigars from the Final

[34] http://www.jepsonfamilyfarms.com/about-us/
[35] Rosalind Essig, "How Tennessee Tobacco Growers Transition Through Change," FarmFlavor.com, March 19, 2018. Available at https://www.farmflavor.com/tennessee/how-tobacco-growers-transition-through-change/
[36] "Perique: A Resurrection Story," Tobacco Business, January 17, 2018. Available at http://tobaccobusiness.com/perique-resurrection-story/
[37] Nicolás Antonio Jiménez, "At the Source of Florida Sun Grown Tobacco," Cigar Snob Magazine, June 1, 2016. Available at http://www.cigarsnobmag.com/news/florida-sun-grown-cigar-tobacco
[38] Lenay Ruhl, "Lancaster County Leads Pennsylvania's Tobacco Business," Central Penn Business Journal, September 25, 2015. Available at http://www.cpbj.com/article/20150925/CPBJ01/309239998/lancaster-county-leads-pennsylvanias-tobacco-business
[39] Tom Lowry, "Tobacco In Amish Country," Cigar Aficionado, March/April 1997. Available at https://www.cigaraficionado.com/article/tobacco-in-amish-country-7556
[40] Gregory B. Hladky, "Foreign Competition, Labor Costs Push Connecticut Shade Tobacco Farmers to the Edge," Hartford Courant, June 15, 2017.
[41] Andrew Nagy, "Broadleaf of Bust," Cigar Aficionado, September 9, 2016. Available at https://www.cigaraficionado.com/article/broadleaf-or-bust-19005
[42] FRIA, p 49.
[43] FRIA, pp 128-134.

Rule, then FDA may count those additional regulatory cost savings (in addition to the costs for handmade cigars that it estimated in the Final Rule) toward the costs for other new rules that could protect public health.

An example of serious underestimates in FDA's cost estimates relate to the cost of adding new warning labels to cigar packaging. FDA presents its analysis of the cost of the Final Rule in its FRIA. A significant part of the analysis is FDA's estimate of the cost of adding warning labels to cigar packages using its Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration.[44]

The labeling cost model is designed to estimate three components of a labeling change: label design costs, inventory costs, and testing costs. However, FDA's analysis counts only label design costs because it assumes away the other two cost components. FDA assumes that manufacturers of products affected by the rule will not test the acceptability of the redesigned labels with consumers because the addition of the warnings is required by FDA. FDA also assumes that all products covered by the Final Rule are branded because FDA does not have a way to identify private label products.[45] That assumption prevents the model from estimating any inventory costs for the label changes, because built into the model is the assumption that branded products do not maintain label inventories in excess of 24 months.

According to the model, label design costs include administrative labor, graphic design labor, prepress labor, recordkeeping, prepress materials, and printing plates.[46] These costs are determined by the type of packaging and printing associated with the product to be relabeled. It costs more to change labels on products with more expensive packaging materials or more colorful printing. Therefore, in order for the labeling model to yield cost estimates that are reasonable approximations of the actual costs, the packages and labels used in the model must be reasonably related to the packages and labels being estimated.

The final report for the model explains that the cost to change all tobacco product packages (including premium cigar boxes) is based only on the cost to change cigarette packages. The final report states, "In the labeling cost model, product subcategories were assigned with package-label types according to the package-label type used by the top-selling product in that subcategory [….] Thus, we assigned the most common package-label type for each product subcategory based on the top-selling products in each product subcategory in 2008."[47] All tobacco products are in one subcategory.[48] Because cigarettes are the top-selling product in the tobacco subcategory, FDA analyzes all tobacco products as requiring

[44] FRIA, page 106.
[45] FRIA footnote 65.
[46] RTI International, Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, Chapter 3 ("Labeling Cost Model Report"). Available at https://www.rti.org/sites/default/files/resources/finalreport_fdalabelingcostmodel_revisedoct2012.pdf
[47] Labeling Cost Model Report, p. 2-7.
[48] Labeling Cost Model Report, Table 2-1, page 2-8.

changes only to the following package-label types: paper labels, paperboard cartons, and paperboard cigarette cartons.[49]

Cigarette packs and cartons are not at all similar to the boxes of premium cigars. Soft packs of cigarettes are made of rotogravure printed paper, hard packs and cartons of cigarettes are made of rotogravure printed, thin paperboard.[50] However, many premium handmade cigars are packaged in sturdy paperboard or wood boxes that are silk-screen printed. The materials and methods for printing premium cigar boxes are nothing like the materials and methods for printing cigarette packs and cartons. Therefore, it is impossible to use FDA's labeling model to estimate the cost of changing labels on premium cigar boxes.

FDA was aware of the limitations of the labeling cost model when it began the Final Rule. In the Preliminary Regulatory Impact Analysis, FDA noted that the labeling cost model could not be used to estimate the number of cigar UPCs that would be affected by the rule and that therefore the agency would have to estimate the number of UPCs without using the labeling cost model.[51] FDA should have been aware of the limitations of the model for estimating the cost of relabeling per UPC. Nowhere in its analyses does FDA admit that its relabeling cost estimates are based only on the cost of changing cigarette labels. Nor does FDA offer any justification for why the cost of changing labels on cigarette packages is a reasonably-acceptable proxy for estimating the cost of changing labels on other tobacco products, especially premium cigars.

Moreover, the labeling cost model is designed to estimate three components of a labeling change: label design costs, inventory costs, and testing costs.[52] That approach works well for all of the products that FDA regulates except for premium cigars. Premium cigars are different from all of the products regulated by FDA. No food, cosmetic, or over-the-counter drug, for example, is a luxury-experience good where the packaging is an integral part of the product. The packaging for all of the products that FDA regulates act almost exclusively as containers for the product and surfaces to display information for consumers. As such, when FDA regulations alter the appearance of such packages, it is not significantly altering the product that the consumer is purchasing. Thus, FDA can make the assumption that it typically makes for its labeling rules of foods, drugs, and cosmetics: "We assume that the package size stays the same and the non-warning information is compressed to fit the reduced allotment of space. We assume that there are minimal costs to consumers from this compression of information."[53]

The agency's deeming of jurisdiction over premium cigars imposes a regulatory regime that is suited for canned corn or bottles of contact lens solution onto a luxury-experience product where it is ill-suited. If FDA is going to regulate luxury-experience products, then it must consider all of the impacts of its rules on them.

[49] Labeling Cost Model Report, Table 2-1, p. 2-8.
[50] 75 Fed. Reg. 69548 (November 12, 2010), footnote 12.
[51] PRIA, p. 42.
[52] Labeling Cost Model Report, Chapter 3.
[53] FRIA, footnote 45.

On luxury-experience products, where the packaging is part of the product, packages are more than merely surfaces for warning and non-warning information. “Compression” of the “non-warning information” on luxury-experience packages actually defaces the packages and imposes significant costs on consumers. Premium cigar boxes serve as displays for the cigars. They serve as presentation packaging for special gifts. The polished wood, the stylishly-designed decoration, the size and shape of the boxes all contribute to the luxury-experience that is part of the experience of premium cigars. Additionally, long after they are empty of cigars, the boxes also have value to collectors and others who appreciate design, style, and craftsmanship in containers.

An accurate estimate of the cost of a regulation requiring that thirty percent of the principal display panel be covered with a warning must include these two additive cost aspects to consumers.

## The Rule Will Not Reduce the Number of Cigars Smoked

There can be no public health benefit of implementing the rule for handmade cigars, because consumers of handmade cigars will not smoke significantly fewer cigars.

Decreases in consumption are usually caused by price increases. FDA does not “expect much increase in price due to variable costs being passed on.”[54] And FDA claims that, “Most of the costs of the proposed rule are fixed costs, which affect prices [only] through product exit.”[55] However, FDA did “not predict the effects of this rule on price, partly because estimating the price increase of newly deemed products due to product consolidation or exit is not straightforward.”[56] In fact, there are so many handmade cigars on the market, and the industry is so competitive, that even with the reduction in the number of products that the rule will cause, producers are unlikely to significantly raise prices in response to the rule.

Additionally, handmade cigar smokers generally do not consume many cigars or spend a significant portion of their discretionary income on cigars. According to a survey conducted by Cigar Aficionado magazine in May 2009, 43 percent of respondents smoke two or fewer cigars per week and 36 percent reported smoking 3-6 cigars per week. At that level of consumption, handmade cigar smokers are not going to be very sensitive to limited changes in price. As Zheng, et al. show, if the particular cigar preferred by a handmade cigar smoker is not available, it is likely that the customer will choose to smoke another handmade cigar that is available or will choose to smoke a machine-made cigar or loose tobacco in a pipe.[57] FDA even repeatedly makes this point in the Final Regulatory Impact Analysis in

[54] FRIA, p. 46.
[55] FRIA, p. 18.
[56] FRIA, p. 18.
[57] Zheng, Y., Zhen, C., Dench, D., and Nonnemaker, J. M. (2017) U.S. Demand for Tobacco Products in a System Framework. Health Econ., 26: 1067–1086. doi: 10.1002/hec.3384.

responses to comments on the proposed rule.[58] At most, the Final Rule will cause there to be fewer *types* of cigars available, but not fewer cigars overall. Covering handmade cigars with the Final Rule will not reduce smoking and therefore provides no public health benefit.

Finally, throughout the history of this rulemaking, FDA has never attempted to estimate any health benefits that would result from this rule, even though FDA has been able to estimate public health benefits for other tobacco regulations.[59] We can only conclude that FDA chose not to report an estimate of benefits because the estimates were too low.

## Conclusion

This report has relied on FDA's own estimates of the cost of the Final Rule to answer FDA's questions on the implications of the rule for the handmade cigar industry.

Compliance with the regulation will be so difficult and costly that it threatens to put almost all U.S. handmade cigar manufacturers and importers out of business. *Using FDA's own cost estimates*, the regulation likely will cause 85 to 90 percent of domestic cigar manufacturers and importers (320-338 small businesses) to go out of business, leading to the loss of 5,300 U.S. manufacturing and importing jobs. Because handmade cigars have the highest cost of compliance per cigar, almost all of the cigar manufacturers and importers that go out of business because of this rule will be manufacturers and importers of handmade cigars. The expected reduction in the number of handmade cigars on the market due to the rule is also likely to cause the closure of at least 494 tobacco retailers and the loss of as many as 19,800 U.S. retail jobs.

The business and unemployment consequences of the Final Rule for the handmade cigar industry are all the more painful because covering handmade cigars with the rule will not contribute to the stated goal of the regulation, "to reduce death and disease from tobacco products."[60] FDA acknowledges as much when it states that the rule will not have much effect on consumers because smokers will have plenty of tobacco alternatives if their preferred product is not available.[61]

Under Executive Order 13771, if agencies reduce regulatory burdens, they may apply the cost savings against future regulations. If FDA exempts handmade cigars from the Final Rule, then FDA could apply that is the amount that FDA could apply $197.8 million (discounted at 3%) under Executive Order 13771 toward other rulemakings that could promote and protect public health.

[58] FRIA, pp. 44 and 47.
[59] For example, see 75 Fed. Reg. 69546 (November 12, 2010) and 76 Fed. Reg. 36728 (June 22, 2011).
[60] 81 Fed. Reg. 28975 (May 10, 2016).
[61] FRIA, pp. 44 and 47.