IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*,	)	
	)	
	)	
	)	
	)	
Plaintiffs,	)	
	)	Civil Action No.
	)	16-1460 (APM)
v.	)	
	)	
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
	)	
	)	
	)	
Defendants.	)	
	)	

BRIEF OF *AMICUS CURIAE* CAUSE OF ACTION INSTITUTE
IN SUPPORT OF PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae Cause of Action Institute ("CoA Institute"), is a 501(c)(3) nonpartisan, nonprofit strategic oversight group committed to ensuring that government decision-making is open, honest, and fair.[1] In carrying out its mission, CoA Institute uses various investigative and legal tools to educate the public about the importance of government transparency and accountability. CoA Institute also frequently represents third-party plaintiffs in actions against the federal government, seeking to scale back regulatory abuses and overreach. CoA Institute believes small business entrepreneurship should not be harmed in the regulatory process. A cost-benefit analysis is a necessary prerequisite to ensuring that the regulatory process adheres to the intent of Congress, is fair, and does not unduly burden small business concerns.

Pursuant to Local Rule 7.0(o), CoA Institute certifies that it is not owned, in full or in part, by any parent corporation or publicly held corporation. Furthermore, CoA Institute received no monetary contribution, from a party or any other person, for filing this brief. Finally, Counsel for CoA Institute authored this brief in full.

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[1] *See* CAUSE OF ACTION INST., *About*, www.causeofaction.org/about/.

INTRODUCTION

To Those Courageous Men And Women Who Came
To This Country In Search Of Personal Freedom,
Economic Opportunity And A Future Of Hope
For their Families[2]

These words, etched on the Immigrant Statue in historic Ybor City, ring hollow in the face of regulatory onslaught by the Food and Drug Administration's ("FDA") "Deeming Rule."[3] FDA is destroying personal freedom, eliminating economic opportunity for small businesses engaged in the premium cigar industry, and crushing hope for a better life for those working so hard to feed and clothe their families. These people and their families deserve better and should be treated fairly. FDA's regulatory abuse in this case is unfair and un-American. Such behavior should not become America's métier.

Ybor City, in Tampa, Florida, was founded by Vicente Martínez e Ybor, an immigrant from Cuba. Many of Ybor City's early residents worked in its cigar factories. For example, immigrants of Italian descent "founded businesses to serve cigar workers, mostly small grocery stores in the neighborhood's commercial district that were supplied by Italian-owned vegetable and dairy farms located east of

[2] Inscription, Immigrant Statue, Centennial Park, Ybor City, Fla. (dedicated May 31, 1992).
[3] Food & Drug Admin., Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (May 10, 2016).

Tampa's city limits."[4] Ybor City's residents also formed ethnic social clubs and benevolent organizations, which offered their members cooperative medical plans and charitable services.[5] In short, they supported each other as a thriving community made possible by the cigar industry and principled entrepreneurship.[6]

The labor pool was certainly diverse.[7] In the late nineteenth and early twentieth centuries, thousands of immigrants of Cuban, Spanish, Italian, German, and Romanian Jewish descent immigrated to work in the cigar factories of Ybor City.[8] At the turn of the twentieth century, nowhere in the United States was as famous for its cigars as Ybor City, which was once known as the "Cigar Capital of the World."[9] The Ybor City Historic District is a National Historic Landmark located northeast of Tampa's downtown where one can find the names of the many immigrant families who came in search of liberty, opportunity, and a better life for their families.[10]

Ironically, in a conspicuous parallel with FDA's "Deeming Rule" and its attendant draconian "approval" process, it was new American tariffs on imported cigars and political trouble in Cuba that compelled Cuban cigar manufacturers to build factories in the United States in the latter part of the nineteenth century.[11] The

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[4] *See Ybor City – Florida's Little Italy*, JOVINACOOKSITALIAN (Apr. 19, 2013), http://bit.ly/2l2LB5C.
[5] *See Ybor City Historic District, Tampa, Florida*, NAT'L PARK SERV., http://bit.ly/2l2xlcW (last visited Feb. 21, 2017).
[6] *Id.*
[7] *Id.*
[8] *See Determining the Facts Reading 1: The History of Ybor City*, NAT'L PARK SERV., http://bit.ly/2lpT7bH (last visited Feb. 21, 2017).
[9] *Id.*
[10] *See Ybor City Historic District*, *supra* note 5.
[11] *Id.*

worm has turned at FDA, and the roles are now reversed. It is FDA that presides over the wholesale destruction of the premium cigar industry. As one commenter to the FDA's Proposed Rule put it:

> Tampa's Ybor City is a cultural heritage. Please STOP this foolish rule. You[] are destroying lives by destroying their livelihood. Please employ common sense to this process. This is America, not Cuba.
>
> God bless[.][12]

The FDA has ceased to concern itself with the costs of its rules on longstanding businesses. Many taxpayers, media outlets, and members of Congress agree.[13]

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[12] Luis Manuel Ramirez, Public Comment on Proposed Rule Deeming Tobacco Products to be Subject to the Fed. Food, Drug and Cosmetic Act, *etc.*, 79 Fed. Reg. 23,142 (Apr. 25, 2014) (comment posted July 14, 2014), *available at* http://bit.ly/2m3gGdl (ID: FDA-2014-N-0189-43061).

[13] *See* J.C. Newman Cigar Co., Public Comment on Proposed Rule Deeming Tobacco Products to be Subject to the Fed. Food, Drug and Cosmetic Act, *etc.*, 79 Fed. Reg. 23,142 (comment posted Sep. 5, 2014), *available at* http://bit.ly/2lIkS1P (ID: FDA-2014-N-0189-81597) (attaching Lizette Alvarez, *After 128 Years of Rolling Them, Tampa Is Close to No Cigars*, N.Y. TIMES (Jul. 22, 2014); Greg Allen, *Fate Of Decades-Old Cigar Factory Dangles By A Phrase*, "All Things Considered," NAT'L PUB. RADIO (Jul. 15, 2014); Letter from Nu-Way Tobacco Co.; Letter from Professor Eric Ballard, PhD.; Letter from Oliva Tobacco Co.; Letter from the Fuente Cos.; Letter from Lancaster Leaf Tobacco Co.; Letter from Sens. Bill Nelson, Marco Rubio, Mary Landrieu, James Inhofe, Joe Manchin, Pat Toomey, Mazie Hirono, David Vitter, & John Walsh; Sen. Marco Rubio, *Column: Save a Tampa Cigar Institution*, TAMPA BAY TIMES (Jul. 23, 2014); Letter from Rep. Kathy Castor; Letter from Rep. David Jolly; Letter from Fla. Gov. Rick Scott & Lieutenant Gov. Carlos Lopez-Cantera; Letter from Fla. Att'y Gen. Pam Bondi; Letter from Tampa Mayor Bob Buckhorn; Letter from the Tampa City Council; Letter from the Hillsborough Cty. Comm'n; Letter from Fla. State Sen. Arthenia Joyner; Letter from the Greater Tampa Chamber of Commerce; Letter from the Ybor City Chamber of Commerce; Letter from the Ybor City Museum Soc'y; Letter from the Ybor City Dev. Corp.; Letter from the East Ybor Historic & Civic Ass'n; Letter from Tampa Preservation, Inc.; Editorial, *Tampa cigar company merits FDA exemption,* TAMPA BAY TIMES (Jul. 10, 2014); Editorial, *Don't snuff out cigar industry*, TAMPA TRIBUNE (Jul. 5, 2014)).

Inexplicably, FDA ignored all comments from the premium cigar industry, Congress, local government, media, and the citizens of the United States, particularly those affected in ways large and small by FDA's power grab.

Had FDA and the Department of Health and Human Services existed during the period of 1885–1930, the ill-conceived regulation of the premium cigar industry would have destroyed Ybor City's factories and put thousands of immigrants out of work. FDA now belatedly and disastrously inserts itself into the biography of the premium cigar industry and generations of cigar growers and producers. But the result is the same. Simply put, FDA's "Deeming Rule" threatens to destroy a $20 billion industry and put at least 20,000 Americans out of work.[14]

As noted in a recent letter by several Members of Congress to Vice President Michael R. Pence, "when Congress passed the Family Smoking Prevention and Tobacco Control Act in 2009, its stated intent was to prevent youth access to tobacco products and the negative health effects of smoking addiction. Neither of these concerns applies to premium cigars which are consumed in moderation and by adult consumers."[15] Additionally, the Congressmen noted that "the Small Business Administration's Office of Advocacy weighed in, noting significant deficiencies in

[14] *See* Letter from Rep. Alan Grayson, U.S. H.R., to Dr. Margaret Hamburg, Comm'r of Food & Drugs, Food & Drug Admin., at 1–2 (Sept. 11, 2014), *available at* http://bit.ly/2lpV5bP (last visited Feb. 21, 2017).

[15] *See* Letter from Reps. Bill Posey, Lou Barletta, & Duncan Hunter, U.S. H.R., to the Hon. Michael R. Pence, Vice President of the U.S., at 1 (Jan. 23, 2017), *available at* http://bit.ly/2m3ghYr (last visited Feb. 21, 2017).

FDA's analysis of the impact regulation would have, particularly as it relates to small businesses which comprise the bulk of premium cigar retailers."[16]

In submitting the Final Rule, "the Administration [and the FDA] failed to conduct a comprehensive economic impact analysis on the implications of the regulations. Bipartisan calls for such a review . . . went ignored."[17]

This necessary cost-benefit analysis can be ignored no longer. *Amicus* CoA Institute respectfully requests this Court to strike down the current Rule, and remand to the agency for further proceedings for all of the reasons set forth below.

ARGUMENT

I. FDA's Violation of Data Quality Standards Led to an Arbitrary and Capricious Rule.

The Information Quality Act ("IQA") is a short piece of legislation enacted in December 2000 as Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001.[18] The IQA directs the Office of Management and Budget ("OMB") to issue guidance to agencies to ensure the "quality, objectivity, utility, and integrity" of information disseminated to the public.[19] OMB issued guidelines in 2002, which provided "policy and procedural guidance" on the IQA and further defined statutory

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[16] *See* Posey Letter, *supra* note 15, at 2.
[17] *Id.*
[18] Consolidated Appropriations Act of 2001, Pub. L. No. 106-554 App. C, § 515, 114 Stat. 2763A-153 (codified at 44 U.S.C. § 3516); *see also* CONG. RESEARCH SERV., THE INFORMATION QUALITY ACT: OMB'S GUIDANCE AND INITIAL IMPLEMENTATION, Order Code RL32532 (2004), *available at* http://bit.ly/2lBqD0D.
[19] *Id.*

terms.[20] In those guidelines, OMB set "quality" as the general term applicable to information disseminated to the public and established "objectivity, utility, and integrity" as defining terms.[21] "Objectivity" asks whether information is presented in a "clear, complete, and unbiased manner" and is "accurate, reliable, and unbiased[.]"[22] OMB adds, "[i]f data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity."[23] "Utility" demands that information be useful for intended users.[24] "Integrity" ensures that data is free from corruption and falsification.[25] FDA has published its own IQA guidance.[26]

Amicus CoA Institute is not asserting that there is a cause of action under the IQA. Instead, these IQA guidelines should be read to inform the Court's arbitrary and capricious analysis.

In analyzing the premium cigar market, FDA failed to consider the best quality data. As Plaintiffs argue in their brief, premium cigars "represent less than 0.1

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[20] Office of Mgmt. & Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter OMB Guidelines].
[21] *Id.* at 8453.
[22] *Id.* at 8459.
[23] *Id.*
[24] *Id.*
[25] *Id.* at 8460.
[26] Health & Human Servs., Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, HHS.gov (Oct. 1, 2002), *available at* http://bit.ly/2lrg4v8 (FDA's guidance is available via drop down menu on this page). FDA notes that its guidance "does not operate to bind FDA or the public." Regardless, FDA is still subject to the IQA itself and OMB's overarching guidelines.

percent of the U.S. tobacco market."[27] The agency also misrepresents the objectivity of its data when it cites the figure that 3.8% of "past 30 day smokers" aged between 12 and 17 reported using a premium brand.[28] By omitting important data, the FDA conceals the fact that it is only citing to 0.001% of people within the relevant age group.[29] The IQA was intended to prevent precisely this sort of behavior by agencies: cherry-picking and misrepresenting data to get to a pre-ordained result. In violating both its own and OMB's IQA guidelines, the FDA has acted in an arbitrary and capricious fashion.

II. FDA Failed to Conduct Cost-Benefit Analysis.

FDA's cost-benefit analysis purports to show that the putative benefits of its Final Rule, increasing overall smoker safety and restricting child access to cigars, outweigh the costs. However, by omitting or glossing over several important costs, FDA fails to conduct a legally sufficient, complete, cost-benefit analysis, as required. First, premium cigar prices will substantially increase for all consumers as a result of the Final Rule. Second, consumer choice and future innovation will be cut off. Third, longtime, small, family cigar companies will have no choice but to sell out to larger corporations, which will then dominate the market as regulation-protected monopolies. All of these are bad for the American consumer. This Court should order the agency to reopen its cost-benefit analysis and conduct a more thorough study.

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[27] Pls. Br. at 16.
[28] *Id.* at 33.
[29] *Id.*

A. Importance and Regulatory History of Cost-Benefit Analysis

Cost-benefit analysis is an important part of modern rulemaking. Such necessary and sufficient analysis includes not only Executive Order ("EO") 12,866, as detailed in Plaintiffs' briefing, but also EO 13,563.[30] Cass Sunstein, who helped implement this order as Administrator of the Office of Information and Regulatory Affairs, describes EO 13,563 as "a kind of mini-constitution for the regulatory state, an immensely important document that places a high premium on analysis of costs and benefits."[31] Section 3 of EO 13,563 commands agencies to "seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation."[32] It further mandates that agencies "ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions."[33] As Sunstein has explained elsewhere, "the requirement of cost-benefit analysis has deterred agencies from proceeding with rules that promise to impose big economic burdens without corresponding gains."[34] "Endorsed for more than three decades and by five presidents, cost-benefit analysis is here to stay."[35]

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[30] Improving Regulation and Regulatory Review, Exec. Order 13,563, 3 C.F.R. § 13563 (2011), *available at* http://bit.ly/2mhfPC5.
[31] Cass Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (and Almost as Many Answers)* 3 (Harvard L. Sch., Pub. L & Legal Theory Working Paper No. 13-11, May 12, 2013), *available at* http://bit.ly/2m7noMg.
[32] *Id.*
[33] *Id.*
[34] Cass Sunstein, *The Stunning Triumph of Cost-Benefit Analysis*, BLOOMBERGVIEW (Sep. 12, 2012), http://bloom.bg/2l32ihl.
[35] *Id.*

B. FDA's Failure to Account for Consumer Costs

Unfortunately, the FDA, in promulgating this rule, failed in its duty to perform meaningful and accurate cost-benefit analysis, ignoring the requirements of relevant EOs and case law. *See, e.g.*, *Bus. Roundtable v. Sec. Exch. Comm'n*, 647 F.3d 1144 (D.C. Cir. 2011).

Increases in regulatory costs generally lead to rising prices for consumers. A recent study found that a 10% increase in total regulations leads to a 0.687% increase in consumer prices.[36] This, of course, substantially affects consumers at the lower end of the income spectrum, where high price volatility can make it impossible to participate in some markets.[37] The increase in already-expensive cigars could, essentially, make them a luxury product that only the wealthy can afford with any regularity.

A similar analysis applies to consumer choice and innovation. Rather than being a benefit, the restriction of consumer access to government-selected products leads to reductions in consumer choice and actually presents a *cost*. Cigars, like any other consumer good, have progressed through the centuries in product quality and integrity. With this rule, though, the FDA arbitrarily decided that all innovation in the premium cigar market must stop at 2007. This presents an enormous cost to both

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[36] Dustin Chambers & Courtney A. Collins, *How Do Federal Regulations Affect Consumer Prices?* 4 (Mercatus Working Paper, Feb. 2016), *available at* http://bit.ly/2mhk948.
[37] *Id*. at 20.

producers and consumers, especially considering that cigars are barely even mentioned in the enabling statute. Mercatus scholars cite Justice Stephen Breyer, explaining that "regulatory agencies can suffer from tunnel vision . . . [as they] tend to focus so zealously on a single goal that they lose sight of where their regulations fit in the larger cost-benefit picture."[38]

"Almost inevitably manufacturers will massively consolidate."[39] The sheer costs of FDA's regulation will be so high that smaller, family-owned businesses will no longer be able to comply. The tradition of premium, hand-rolled cigars handed down by generations will turn into a corporate mill. This, as detailed above, will lead to higher prices, reduced choice and quality, and the curtailment of innovation in the market. The FDA's cynical nod to cost-benefit analysis fails for many reasons, including its "tunnel vision" and inability to consider the cost to consumers, producers, and retailers.

The FDA admits that it failed to do any analysis on consumer choice. "We lack a baseline estimate of consumer valuation of tobacco product variety, making it impossible to estimate how consumers who continue to use tobacco products would value the potential loss of variety due to product exit under this final rule."[40] Instead,

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[38] Christopher Koopman & Nita Ghei, *Behavioral Economics, Consumer Choice, and Regulatory Agencies*, MERCATUS CTR. (Aug. 27, 2013), *available at* http://bit.ly/2kTZimt.

[39] David Bufkin, *Cigars Won't Hurt You, But the FDA's New Cigar Tax Will*, THE FEDERALIST (Oct. 5, 2016), http://bit.ly/2lGNDM1.

[40] Food & Drug Admin., FINAL REGULATORY IMPACT ANALYSIS: DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED

FDA just hand waves away this essential element of cost-benefit analysis by pretending that this data does not exist. This Court should require FDA to revisit and construct a complete analysis of this important cost.

CONCLUSION

For the reasons discussed above, *Amicus* CoA Institute respectfully requests that the Court vacate and remand FDA's final rule.

Dated: February 21, 2017

Respectfully submitted,

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WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS, at 44 (May 2016), *available at* http://bit.ly/2l2QhZj.

CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(d)(1), I hereby certify that on February 21, 2017, I filed this Motion with the United States District Court for the District of Columbia using the CM/ECF system, which will send electronic notice of this filing to all parties registered to receive such notice.

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