IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

BRIEF OF THE STATES OF ARIZONA, LOUISIANA, MICHIGAN AND TEXAS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS

Dated: February 21, 2017

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The States of Arizona, Louisiana, Michigan, and Texas (*Amici* States) respectfully submit this brief in support of Plaintiff Associations' Motion for Summary Judgment. Pursuant to Local Civil Rule 7(o)(1), *Amici* States may file an *amicus curiae* brief without the consent of the parties or leave of Court. Nevertheless, in keeping with the spirit of Local Civil Rule 7(m), *Amici* States have contacted counsel for Plaintiffs and Defendants to inform them of this filing.

Amici States are concerned with the proper regulation of tobacco products and especially the prevention of illegal youth smoking. To these ends, *Amici* States together with every other state, have established policies and reached settlement agreements with cigarette manufacturers that both discourage youth smoking and fund education efforts on the dangers of smoking. Accordingly, *Amici* States welcomed the passage of the Family Smoking Prevention and Tobacco Control Act of 2009 ("Family Smoking Prevention Act"), Tobacco Regulation, Federal Retirement Reform, Pub. L. 111-31, 123 Stat. 1776 (2009) *et seq.*, as an additional step in that same direction. However, on May 10, 2016, the Food and Drug Administration issued a rule contrary to the purpose and structure of the Family Smoking Prevention Act. *See* Final Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of

Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (to be codified at 21 C.F.R. Parts. 1100, 1140, and 1143) (May 10, 2016) ("Final Rule" or "Rule"). This action, brought by the Cigar Association of America, the International Premium Cigar and Pipe Retailers Association, and the Cigar Rights of America (together, the "Plaintiff Associations") challenges the Final Rule and seeks to enjoin its implementation. *Amici* States agree that the Rule requires substantial modification and that this Court should set it aside as unlawful.

SUMMARY OF ARGUMENT

While supportive of the entirety of Plaintiff Associations' Motion for Summary Judgment, *Amici* States limit their discussion here to two main issues. First, the FDA failed to provide an adequate cost-benefit analysis determining that the benefits of deeming premium cigars to be regulated tobacco products outweigh the undeniably severe costs, particularly to thousands of small businesses. In doing so, the agency ignored the principles that Congress set for balancing the costs of regulation against its benefits: Congress sought "appropriate" regulations that permit the continued sale of cigars and pipe tobacco to adults. Secondly, the FDA failed to adequately address the way in which deeming cigars will undermine the public health programs funded by state excise taxes on non-cigarette tobacco products.

The Administrative Procedure Act (APA), 5 U.S.C. § 706 (2)(C) states that an agency action is barred when said action is exceeds the agency's "statutory jurisdiction, authority, or limitations." *Id.* at § 706 (2)(C). Agencies such as the FDA are created and empowered by organic statutes that establish their jurisdiction, purpose, and powers. These agencies as legislative creations are therefore empowered and directly restrained by the rules that Congress sets. The Final Rule, promulgated seven years after the Family Smoking Prevention Act was enacted, departed from the statutory scheme and the clearly expressed public policy goals that established the statute's purpose.

In broad terms, the Family Smoking Prevention Act granted authorization to the FDA to regulate cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. However, the statute also extended its purview to "any other tobacco products that the Secretary by regulation deems to be subject to this chapter." *See* FD&C Act § 901(b), 21 U.S.C. 387a(b). While the FDA was authorized to "address issues of particular concern to public health officials," they were instructed to focus especially on "the use of tobacco by young people." 123 Stat. 1776, § 3(2). Congress explicitly expressed a desire that this regulation not interfere with "the sale of tobacco products to adults in conjunction with measures to ensure they are not sold or accessible to underage purchasers." *Id.*, § 3(7).

Contrary to this instruction, the FDA's Final Rule deemed all cigars—including premium cigars—subject to the statute. By issuing this Final Rule, the FDA rejected its own "Option 2," which had been advanced in the Proposed Rule and would have explicitly excluded premium cigars from the regulation. 79 Fed. Reg 23,143, 23,150.

The decision to regulate premium cigars was not appropriate, not supported by quantitative analysis or reasoned decision making because the costs outweigh the benefits. The FDA failed to provide quantitative measurement of benefits that were aligned with the purposes of the Family Smoking Prevention Act and failed to justify its opinion that these benefits outweighed the extreme costs, which will shut down premium and pipe tobacco retailers and manufacturers and effectively make cigar and pipe tobacco products used by adults for decades unavailable for sale.

Finally, *Amici* States are concerned that the Final Rule will unsettle the evidence-based state tobacco control programs that are funded in many states by excise tax revenues on tobacco products. Excise taxes on tobacco products fund many other state budgetary priorities as well. Despite this, the FDA summarily dismissed comments raising this issue with the unsupported conclusory assertion that there will be "no net social cost or benefit associated with any reduction in

excise tax collections."[1] This is a truly remarkable statement and is akin to an assertion that governments should not be collective taxes at all, if the money has equal social value in the hands of the private sector. Through its attack on the cigar industry, the FDA's rule will reduce resources available to tobacco control programs that have been proven to reduce youth use and initiation in favor of a blunderbuss regulation the FDA barely can even speculate will have such an effect.

I. FDA FAILED TO DEMONSTRATE THE APPROPRIATENESS OF REGULATING PREMIUM CIGARS

The FDA must justify its regulatory decision to subject premium cigars to burdensome regulatory scheme by the principles that Congress established in the Family Smoking Prevention Act. Congress clearly demanded that the agency demonstrate that any regulation of cigars and pipe tobacco produce benefits that exceed its costs and not destroy large segments of the tobacco industry. This mandate is reflected throughout applicable law. First, Congress directed FDA to only "impose *appropriate* regulatory controls on the tobacco industry." 123 Stat. 1776, § 3(8) (emphasis added). That is a Congressional directive for the agency to engage in a cost-benefit analysis in any rulemaking. *See Michigan v. EPA*, 135

[1] Food and Drug Administration, Final Rule, FDA-2014-N-0189: Final Regulatory Impact Analysis ("FRIA"), May 10, 2016, AR023112, at 120.

S.Ct. 2699, 2706–07 (2015) (holding term "appropriate" to encompass cost/benefit factors). Second, Congress instructed the agency not to destroy large segments of the tobacco agency and to implement regulation in a manner that would ensure that long-standing tobacco products would remain available for sale to adults. 123 Stat. 1776, § 3(6). Third, agencies must prepare "a qualitative and quantitative assessment of the anticipated costs and benefits of [a rule], including the costs and benefits to … the private sector" whenever a rule will impose over $100 million in inflation-adjusted costs. 2 U.S.C. § 1532(a)(2). Fourth, the APA's requirement of "reasoned decision making" likewise requires agencies to "look at the costs as well as the benefits" of the rules they promulgate. *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52–54 (1983).

FDA correctly determined that a cost-benefit analysis of the Rule is required, particularly because the Rule will cost the private sector nearly $1 billion, with a "significant" effect on small businesses. 81 Fed. Reg. at 29,074. But the cost-benefit analysis present in the Final Rule fails to qualify as reasoned cost-benefit analysis for several reasons.

First, the Rule's cost-benefit analysis fails because FDA failed to provide quantitative estimates of the benefits of regulating any of the newly deemed products including premium cigars. Rather than compute even an approximation of the benefits that the Rule will provide, FDA says that "[t]he direct benefits of" the

Rule "are difficult to quantify, and we cannot predict the size of these benefits at this time." 81 Fed. Reg. at 28,981, 29,075. The difficulty of the task does not excuse this omission.

Secondly, because Rule's benefits must be reasonably linked to the purposes set for the regulatory scheme by Congress, the FDA needed to show that premium cigars were used by youth. *See, e.g.*, Act § 3(2) (Act designed to provide authority to address "issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco"); *id.* § 3(6) (purpose of the Act "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers"). Congress gave FDA regulatory authority to deem other tobacco products for specific purposes and subject to various parameters. Unless the benefits are germane to those purposes, they are irrelevant to the cost-benefit analysis. What Congress did not authorize is to impose massive costs of producers and retailers of products rarely used by youth and reduce the number of tobacco products by driving companies out of business through the costs of regulation. On this ground, the decision to deem premium cigars is even more unsupportable. Premium cigars constitute a *de minimus* portion of youth tobacco initiation and use and deeming them is completely inappropriate. Holding that the FDA may look to

whatever benefits it desires in deeming tobacco products would only be creating a nondelegation problem.

Finally, the Rule's costs are dramatic and may result in the shuttering of an entire industry. To the extent that the FDA decided that the benefits of regulating premium cigars outweighed the costs of doing so, that decision was arbitrary and capricious and subject to this Court's review.

A. FDA Failed to Quantify Benefits

The Rule's odd decision to quantify costs, not to quantify benefits, and nevertheless to conclude that the benefits outweigh the costs is unsustainable especially regarding premium cigars. This Rule is the sort of rule for which the precedent most explicitly demands cost-benefit analysis. In *Michigan v. EPA*, the EPA decided to regulate power plants as sources under a specific section of the Clean Air Act, triggering a series of burdens and authority to impose further regulation. That same kind of initial step choice is at issue in this case: "The final deeming action differs from most public health regulations in that it is an enabling regulation." 81 Fed. Reg. at 29,075.

The FDA was able to estimate a cost of the Final Rule: an estimated 20-year-cost of $783.7 million to the private sector. 81 Fed. Reg. at 28,980. By mere assertion, the FDA concludes that various, unquantified benefits will surely exceed

this not insignificant sum. *Id.* at 28,980. The "difficult to quantify" "direct benefits" include regulatory prevention of mislabeling, the prevention of "greater health risks" from new products, and the benefits of warning labels. *Id.* The FDA never described, however, how the rule would reduce the incidence of underaged, or really any, tobacco use. This is, in part, due to the agency failing to identify what it expected this newly imposed regulatory regime to find in the cigar and pipe tobacco industries. The agency cited not a single example of how premium cigar products were misbranded, for example, much less how it was harming the public health. Nor did the agency produce any evidence of manipulation of ingredients in cigars and pipe tobacco so as to make them more addictive or attractive to youth, as Congress had done in the Act before regulating cigarettes. *Compare*, *e.g.*, Act §§ 2(45)-(47) (describing judicial findings regarding marketing to youth and nicotine manipulation in the tobacco industries). Nonetheless, the agency subjected cigars and pipe tobacco to a crushingly expensive premarket review process, without explaining what the agency expected to detect. These failings left the agency unable to explain the mechanism or the causal path by which the public health will be benefited. Effectively, the FDA is saying that because a regulation will result in a more regulated world, the benefits to end users need not even be analyzed. Such handwaving cannot withstand, and traditionally has not survived, judicial scrutiny.

The agency knows it has not amassed the evidence necessary to show that the Rule will benefit the public health and by how much. FDA suggests that the Rule is justified because it will provide FDA with the ability "to obtain critical information regarding the health risks of newly deemed tobacco products." 81 Fed. Reg. at 28,975. But cigars and pipe tobacco have been on the market for centuries, and the agency is admitting it has not bothered to do the homework necessary to identify the health risks of those products and show how the Rule would reduce them. The Act, the APA, and common sense bar the agency from regulating first and asking questions later. The agency's rationale is wholly circular and question begging: FDA cannot rationally justify a rule intended to address health risks by pointing to the need for information to determine whether those risks exist in the first place.

The time for rigorous cost-benefit analysis is now, not decades later after the agency has destroyed large segments of an industry employing thousands. This Court must enjoin this Rule until such point that the FDA is able to complete the effort of describing the benefits to the public with definite numerical values.

B. FDA Failed to Justify Its Decision to Regulate Under the Purposes of the Act

1. The Prohibition of Adult Smoking of Premium Cigars is Not a Proper Purpose.

To the extent that the FDA's unquantified benefits can be weighed against the quantifiable costs of the regulation, that analysis must be restricted to those benefits that actually promote the purposes of the authorizing legislation. Any other requirement would be a threat to democracy: An unelected agency head pursuing ends with which the Nation's elected representatives did not charge it untethers the agency's work from the will of the People. Generalized benefits cannot be placed on the scale to justify a decision to regulate without creating a nondelegation problem. *See* Section B.3 *infra*.

Thus, in the Family Smoking Prevention Act, Congress determined that cigarettes, smokeless tobacco, and "roll-your-own tobacco" (essentially homemade cigarettes) would be subject to immediate regulation. FD&C Act § 901(b), 21 U.S.C. § 387a(b). That determination was expressed as a Congressional Finding in section 2(31) of the Act that regulating cigarettes and smokeless tobacco was of crucial importance to preventing the life-threatening health consequences associated with their use. *See* 123 Stat. 1776, 1779 (stating that FDA's final regulation from 1996, after incorporation into current regulations, would "directly and materially advance the Federal Government's substantial interest in reducing

the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use.") There was no suggestion that any tobacco products other than the three categories Congress targeted posed a significant threat to public health.

Put another way, Congress was not sure that cigars and pipe tobacco should be regulated at all, much less with the devastating costs for those industries contemplated in the Final Rule. Congress desired for an expert agency that is supposed to compile scientific data and evidence before acting to be able to exercise a degree of regulatory discretion, but only for specific purposes and subject to limitations. Specifically, Congress empowered the FDA "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people," while also requiring the FDA "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers." 123 Stat. 1776, 1781-82. The scope of "appropriate regulatory controls" authorized by the Act must be informed by a harmonized reading of both clauses.

Accordingly, the FDA's cost-benefit analysis of this Rule cannot justify its costs by reference to generalized prevention of smoking of all tobacco products. Instead, costs of regulation must be justified by its benefits in reducing the use of

tobacco by young people while ensuring that tobacco products remain available to adults. Shuttering small businesses who have crafted artisan cigars and pipe tobacco for decades flies in the face of this congressional instruction.

2. Premium Cigars Constitute a De Minimus *Portion of Youth Tobacco Use.*

The FDA, by failing to rationalize the deeming of premium cigars by reference to these parameters, has acted arbitrarily and capriciously in issuing this Rule. While Congress gave FDA deeming authority, it also gave instruction for how that authority could be exercised.

Contrary to this instruction, the FDA's Final Rule deemed all cigars—including premium cigars—and pipe tobacco subject to the statute. By issuing this Final Rule, the FDA rejected "Option 2" which would have explicitly excluded premium cigars from the regulation. Option 2, as detailed in the Proposed Rule, exempted cigars comprised solely of tobacco, made largely by hand, and over a certain price threshold. 79 Fed. Reg. at 23,150–52. Rejecting this distinction in such a way that all cigars were swept into the regulation is a decision not supported by facts.

Particularly, the summary rejection of Option 2 was not supported by any suggestion that premium cigars make any significant contribution to the initiation of youth tobacco use. Young adults, defined as individuals 18 to 29 years old who can legally purchase tobacco, do sometimes purchase these products. *See* 79 Fed.

Reg. 23,151. However, usage among adolescents, individuals 12 to 17 years old who cannot legally purchase tobacco, is measured in the factions of one percent.

Indeed, adolescents aged 12 to 17, do not seem to favor cigars, much less premium cigars. The 2015 National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that a small and declining percentage of adolescents were current cigar smokers.[2] Since 2009, the annual percentage of adolescents who have smoked a cigar in the past month has never surpassed 4.0% and has dropped to between 2.1% and 2.3% for the years 2013 through 2015. This even though the SAMHSA data makes no distinction between "little cigars"—a category that government data indicate are more frequently used by this extremely small percentage of adolescents—and other cigars.[3] The same SAMHSA study found that 4.2% of adolescents had smoked a cigarette in the past month in 2015, twice as many as had used a cigar. [4]

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[2] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2015/NSDUH-FFR1-2015/NSDUH-FFR1-2015.pdf, 16-17.

[3] *See* Department of Health and Human Services Office of Inspector General, "Youth Use of Cigars: Patterns of Use and Perceptions of Risk" (Feb. 1999), available at https://oig.hhs.gov/oei/reports/oei-06-98-00030.pdf, AR026066.

[4] Center for Behavioral Health Statistics and Quality at 14.

The entire extent of evidence that the FDA supplies to show youth use of premium cigars consists of a single study.[5] In that study, researchers used data from the 2010-2011 NSDUH and Nielsen market scanner data to define a study sample consisting of 6,678 past 30-day cigar smokers who reported smoking a usual brand of cigars. *Id.* This analysis showed that 3.8 percent of youth aged 12 to 17 *who smoked cigars in the last 30 days* identified a brand of premium cigars as the product they used. What the agency neglected to mention is that 30-day cigar smokers are only approximately 3.3 percent of this persons aged 12 to 17. That is 3.8 percent of the 3.3 percent of persons aged 12 to 17 who have smoked any cigar in the last 30 days, or one of every thousand of that age group.

So here, the agency has decided to run every premium cigar through a crushingly expensive premarket review and testing process, to require registration and inspection of every premium cigar manufacturer, and to mandate massive warnings on every cigar product, and collectively to impose costs that the agency admits will cause many cigar manufacturers from the marketplace and end the jobs of thousands. All for what?: To address the .001% of persons aged 12 to 17 who smoke premium cigars, without even explaining in any detail how the Rule would

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[5] Delnevo CD, Giovenco DP, Ambrose BK, *et al.*, "Preference for Flavoured Cigar Brands Among Youth, Young Adults and Adults in the USA," *Tobacco Control*, Published Online First: 10 April 2014. doi: 10.1136/tobaccocontrol-2013-051408, AR020897

reduce that infinitesimally small number. In this Rule, the FDA has taken the jackhammer of deeming premium cigars to a problem as small as a fly.

3. Divorced from an Intelligible Principle, FDA's Deeming Power Would Constitute an Unconstitutional Delegation of Legislative Authority.

The FDA was granted discretion on whether or not to deem any statutorily defined tobacco product as regulated under the rule. However, that is merely the outer limits of their discretion. The statute must also provide the FDA with a principle by which it can exercise that discretion. Here there is such a principle, *see* section A.1 *supra*, but if this Rule is upheld that principle will be erased.

The FDA's assertion that regulation of premium cigars is good because it would mean that there is more regulation of tobacco products would effectively deny that there is any intelligible principle to guiding that determination. Premium cigars contain tobacco and are within the boundaries to be deemed a regulated tobacco product, but that is not enough. Nondelegation doctrine teaches that Congress must set both the "boundaries" of the Executive's discretion and supply an "intelligible principle" for the exercise of that discretion within those boundaries. *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989). Allowing the FDA to count all benefits, even ones not mentioned in the authorizing statue, would decouple the exercise of the FDA's discretion so much from the decisions of

Congress as to deprive the people of the structural protections guaranteed by the first section of Article I.

C. FDA Failed to Adopt Less Costly Alternatives

1. Premium Cigars Differ from Originally Regulated Tobacco Products.

After utilizing its authority to deem premium cigars as subject as subject to the Act, the FDA's Rule subjected this industry to "all statutory provisions that apply to all tobacco products" regulated by the Act. 81 Fed. Reg. at 29,000. The FDA claimed that this was a mandatory result of deeming premium cigars covered by the act, without regard for whether the implementation of these rules would destroy large parts of the market. *Id.* The way the Rule is structure requires virtually every cigar to go through the full premarket review process.[6] This is an unnecessary and absurd burden for premium cigar manufacturers. By *definition*, premium cigars are not mass produced, yet for each short run batch there must be a costly pre-market review. This is an illogical result that runs contrary to the structure and purpose of the Family Smoking Prevention Act.

Premium cigar consumers expect a constantly changing set of product offerings that differ primarily only as to taste. Limited run products, variegated by

[6] *See, e.g.*, Cigar Association of America Comments (FDA-2014-N-0189-75911) at 7.

the quality and characteristics of the tobacco leaf harvested, are a core part of the premium cigar business model.[7] Indeed, while there are just over 5,000 active UPCs for cigarettes, smokeless tobacco, and roll-your-own tobacco products,[8] there are between 10,000 and 20,000 unique premium cigar stock-keeping units.[9]

2. Small Businesses in the Premium Cigar Marketplace Will Be Devastated.

Because the premium cigar marketplace is structured as it is, the Rule will have massively disruptive effects. The FDA admits that, "the costs of the final rule depend more on the number of products than the number of units . . . sold." FRIA at 132. In fact, compliance costs even for small premium cigar manufacturers or importers are estimated to exceed $235,000 annually. *Id.* to Thus, small firms that offer "a large number of low volume products"—a fair description of the vast majority of participants in the premium cigar marketplace—are likely to be "significantly affected by this rule" up to and including exiting the market. *Id.*

The FDA failed to give appropriate consideration to regulatory alternatives which could have lessened these draconian results. The Rule will have a devastating impact on small businesses. It will force premium cigar manufacturers

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7 *See* Cigar Association of America Comments at 3.

8 FRIA at 27-28.

9 81 Fed. Reg. at 29,079.

to either seek expensive premarket clearance for each of their diverse offerings or radically narrow their product line. Either choice will transform the premium cigar industry beyond recognition for little or no public health benefit.

By choosing to regulate premium cigars in a way that will crush small businesses without providing adequate justification for that choice, the FDA has violated *Michigan v. EPA*, the Regulatory Flexibility Act, and the APA. *See*, *e.g.*, *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) ("the APA together with the Regulatory Flexibility Act require that a rule's impact on small businesses be reasonable and reasonably explained")

II. FDA FAILED TO ADEQUATELY JUSTIFY ITS CHOICE TO DIMINISH STATE EXCISE TAXES

Deeming cigars to be a regulated tobacco product threatens the evidence-based public health benefits paid for by state excise tax collections from non-cigarette tobacco products. Multiple commenters complained that the Rule would lead to a reduction in excise tax revenue, a natural result of driving manufacturers and retailers out of business through costly regulation. Excise tax revenue is used by the states to fund tobacco control programs, children's health care, and other important budgetary priorities. FRIA at 49. The FDA conceded that this rule would "result in a decrease in government tobacco product excise tax revenues" but argued that this change would result "in no net social cost or benefit." *Id.*

This is a facile oversimplification. Nationwide, state excise tax collections from non-cigarette tobacco products totaled $1.6 billion in 2014.[10] That figure represented 7.8% of state total tobacco excise tax revenues. *Id.* These funds are essential to state public health efforts.

The Rule asserts that lower excise tax revenues principally causes "gains to former payers and losses to former recipients" and that since these transfers offset each other, "there is no net social cost or benefit associated with any reduction in excise tax collections that may occur as a result of this final rule." FRIA at 120. This assertion is nothing more than begging the question. The agency admitted it could not demonstrate or begin to quantify the public health benefits the Rule would cause. By stark contrast, the smoking cessation and tobacco control programs funded by State excise taxes have been demonstrated through scientific evidence to reduce underaged smoking. *See*, *e.g.*, Decl. of Cecil Reynolds, Docket Number 22-1, at ¶¶ 81-83 (documenting the extensive evidence that State-funded public health programs, including enforcement efforts against underaged purchase and education campaigns that address the evidence-based root causes of underaged tobacco use, actually reduce underaged smoking). Such economic theorizing myopically ignores the public health initiatives funded by state governments with

[10] Orzechowski and Walker, *The Tax Burden on Tobacco, Historical Compilation*, Vol. 49, (2014), available at https://www.healthdata.gov/dataset/tax-burden-tobacco-volume-49-1970-2014.

these revenues. Contrary to the FDA's assertions, the beneficiaries of programs funded by these revenues include many of society's most vulnerable members. The evidence in the record shows that the Rule risks reducing the public health benefits of government tobacco control programs generally, pulling funds from State programs demonstrated to actually work in favor of an FDA regulatory regime the benefits of which the agency cannot quantify. By giving the back of its hand to the reduction in State excise tax revenue, the FDA has thus failed "to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, and the rule must be enjoined and remanded to the FDA for further proceedings.

RESPECTFULLY SUBMITTED this 21st day of February, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief *Amicus Curiae* for the States of Arizona, Louisiana, Michigan, and Texas with the Clerk of the Court for the United States District Court for the District of Columbia by using the appellate CM/ECF system on February 21, 2017. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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