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)

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7(h), plaintiffs Cigar Association of America (CAA), Cigar Rights of America (CRA), and International Premium Cigar and Pipe Retailers Association (IPCPR) (collectively, "Plaintiffs") move for summary judgment against defendants United States Food and Drug Administration, United States Department of Health and Human Services, Thomas E. Price, MD, and Stephen Ostroff, MD (collectively, "FDA") on all of their claims.[1]

On May 10, 2016, the FDA promulgated a rule "deeming" all cigars and pipe tobacco subject to the Family Smoking Prevention and Tobacco Control Act ("TCA"), and imposed an onerous regulatory scheme on these newly deemed products. *See* Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (the "Deeming Rule"). It promulgated a separate rule that same day that imposed user fees on some,

[1] Drs. Price and Ostroff are the current Secretary of Health and Human Services and Acting Commissioner of the United States Food and Drug Administration, respectively. In that the former Secretary and Commissioner were sued in their official capacities, the successor of each is automatically substituted into complaints in which each is a defendant. *See* Fed. R. Civ. P. 25(d).

but not all, newly deemed products. *See* Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28,707 (the "User Fee Rule").

The Deeming Rule and User Fee Rule must be set aside. For the reasons stated below and further addressed in the accompanying Memorandum of Law, these rules are arbitrary, capricious, an abuse of discretion, and not in accordance with law; are contrary to constitutional right, power, privilege, or immunity; and exceed statutory jurisdiction, authority, or limitations, or are short of statutory right. 5 U.S.C. § 706(2)(A)-(C). In support of this argument, Plaintiffs state:

1. In the Deeming Rule, the FDA incorrectly concluded that it had no choice but to impose all aspects of the FDA's premarket review and testing scheme on cigars and pipe tobacco. The most prominent example of the agency's error was to apply a 2007 predicate date to exempt or adjust the process for products to go through premarket review for cigars and pipe tobacco first regulated in 2016. The result is a premarket review process that is far more burdensome for cigars and pipe tobacco than for cigarettes and smokeless tobacco—the products of most immediate concern to Congress. The agency's action is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations or short of statutory right. The Deeming Rule must be vacated to allow the FDA to exercise its full statutory discretion and consider whether and how to efficiently and appropriately regulate cigars and pipe tobacco.

2. The FDA also imposed the Deeming Rule on cigars and pipe tobacco without clarifying the premarket substantial equivalence pathway available to cigars and pipe tobacco. The FDA had statutory authority to do so, and appropriate guidance could have ameliorated

some of the burden of the premarket review scheme. The agency's action is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

3. Cigarettes and smokeless tobacco products were permitted to remain on the market while product applications were pending with the FDA. The FDA initially considered, but ultimately rejected, a similar enforcement forbearance policy for cigar and pipe tobacco products. The agency's discriminatory treatment of cigars and pipe tobacco is arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

4. The FDA itself proposed a reasonable alternative to regulation of the entire cigar industry. The agency's so-called "Option 2" would have exempted premium cigars, which are expensive and minors almost never use, and the product variation of which results from factors such as weather and location, from the burdensome and unjustified requirements of premarket testing and review. The agency, however, failed to adequately consider this reasonable alternative. This was arbitrary, capricious, an abuse of discretion, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

5. The FDA had the authority to require "user fees" from all newly deemed products. It eschewed this authority, however, and refused to impose user fees on e-cigarettes in the User Fee Rule. Its selective imposition of user fees is arbitrary, capricious, an abuse of discretion, and not in accordance with law; contrary to constitutional right, power, privilege or immunity; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. The User Fee Rule violates the Equal Protection component of the Fifth Amendment's Due Process Clause.

6. The FDA's cost-benefit analysis underlying the Deeming Rule was based on speculative benefits that the agency made no effort to quantify or justify through imposition of the premarket review regime. It relied on inaccurate data, improperly assumed that costs and benefits could be based on the agency's experience regulating other tobacco products, and failed to give due regard to the distinctly harsh impact of the regulation on the premium cigar and pipe tobacco markets. As a result, the Deeming Rule is arbitrary, capricious, an abuse of discretion, and not in accordance with law; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and violates the Regulatory Flexibility Act.

7. The FDA's warning label requirements, which mandate labels covering 30% of each of the two principal panels of cigar and pipe tobacco products, violate the First Amendment. They crowd out manufacturers' own trade dress and communications with customers, and are an unconstitutional restriction on this commercial speech. They also fail review as compelled speech. The warning label requirements further violate the Act and the APA, obviating the need to reach the First Amendment issues. The agency failed to make the findings required by the TCA to justify imposition of the warning labels, and imposed the new warning label requirements without accounting for the efficacy of existing warning label regimes. The warning label requirements are arbitrary, capricious, an abuse of discretion, and not in accordance with law; contrary to constitutional right, power, privilege, or immunity; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

8. The FDA incorrectly interprets the TCA to treat retailers who blend pipe tobacco as "tobacco product manufacturers" subject to the full scope of regulatory burdens under the Rule. The agency's application of "manufacturer" obligations on small business retailers who are performing an act on finished (and fully regulated) tobacco products that consumers could do

on their own is arbitrary, capricious, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

9. The FDA also improperly treats pipes as "components" of a tobacco product and therefore subject to regulation. Its interpretation runs contrary to the statute and imposes wholly unreasonable obligations on pipe manufacturers, including many individual and small business artisans. The agency's imposition of regulatory authority over pipes is arbitrary, capricious, and not in accordance with law; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

For these reasons and those set out in the accompanying Memorandum of Law, Plaintiffs request that the Court grant their motion for summary judgment on all claims and: (1) vacate and set aside the Deeming Rule; (2) vacate and set aside the User Fee Rule; (3) declare that the User Fee Rule violates the Fifth Amendment; (4) declare that the Deeming Rule warning label requirements violate the First Amendment; (5) enter a permanent injunction restraining the FDA from implementing or enforcing the Deeming Rule or User Fee Rule; (6) award Plaintiffs their litigation costs and attorneys' fees; and (7) order such other and further relief as the Court deems just and proper.

For the foregoing reasons and those stated in the accompanying Memorandum of Law, Plaintiffs' motion for summary judgment should be granted.

A proposed order is filed herewith. Pursuant to Local Rule 7(f), Plaintiffs respectfully request oral argument on this motion.

Dated: February 13, 2017

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF
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Dated: February 13, 2017

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INTRODUCTION

In its Final Rule, the FDA "deems" cigars and pipe tobacco subject to a costly regulatory scheme that Congress immediately applied to cigarettes and smokeless tobacco in 2009. *See generally* Final Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"). The Deeming Rule threatens to destroy cigar and pipe tobacco industries, including manufacturers and retailers, shuttering family-owned small businesses across the Nation. To bring about this result, the FDA relied on a 77-page statute—the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (2009) (hereinafter the "TCA" or the "Act")—that mentions cigars and pipe tobacco only *twice*. The agency's rule misinterprets the Act, disregards comments demonstrating impending agency error, rolls over contrary evidence in the record, casts aside less costly alternatives advancing the public health, and tramples on manufacturers' First Amendment rights. It is a case study in arbitrary and capricious rulemaking.

First, the Deeming Rule mechanically imposes the entire weight of the FDA's premarket review and testing scheme on cigars and pipe tobacco without making any modifications for either the passage of time or the unique characteristics of these products. Because Congress believed that cigarettes and smokeless tobacco presented the most immediate public health concerns, it mandated immediate regulation of them to root out—product-by-product—allegations that cigarette companies had manipulated nicotine and other ingredients to make cigarettes more addictive or attractive to youth. By contrast, Congress took no view on whether or how cigars and pipe tobacco—products with a different history and presenting different public health issues—should be regulated.

The Deeming Rule results in cigars and pipe tobacco being regulated more harshly than cigarettes, a paradox that a Congress agnostic about any regulation of cigars and pipe tobacco

never intended. This is, in part, due to the passage of time. Congress exempted cigarettes and smokeless tobacco products that were on the marketplace as of February 15, 2007—and their "substantial equivalents"—from the arduous premarket review process. That meant only those cigarette products created within the two years before the Act had to navigate premarket review, and even those new products could use a less burdensome path if "substantially equivalent" to a pre-2007 product. The FDA, however, refused to update the 2007 predicate date for its 2016 regulation of cigars and pipe tobacco. If the Rule were to stand, cigars and pipe tobacco products created within the *last decade* would have to run the gauntlet of premarket review. And the less burdensome substantial equivalence pathway that was available to cigarettes and smokeless tobacco would be effectively denied to cigar and pipe tobacco manufacturers who would have the nearly impossible task of comparing current products with those marketed a decade ago.

Compounding this crushing burden on cigars and pipe tobacco is their vast variety: Each cigar manufacturer has many times more unique products than cigarette companies. While the FDA's hunt—product-by-product—for ingredient manipulation might have been justified given the allegations in the cigarette industry, there is no comparable history with cigars and pipe tobacco. Cigar and pipe tobacco businesses will close under the weight of regulation, wholly inconsistent with Congress's expressed intent to not ban segments of the tobacco industry and drive companies out of business.

The FDA said its hands were tied by the statute: It could not adjust the predicate date or anything else for the timing of its regulation or the different industries being regulated. The FDA got the scope of its statutory discretion wrong, and the remedy is to vacate the Rule for the agency to exercise its correctly defined authority. The Act plainly leaves *whether and how* to

regulate cigars and pipe tobacco to the FDA. The FDA was supposed to reach tobacco products other than cigarettes and smokeless tobacco "by regulation" and use its "flexible" authority to craft a scheme for products Congress was not sure should be regulated at all. *See* 21 U.S.C. §§ 387 note (Purpose), 387a(b) (2012). Congress did not set a regulatory cliff, where the agency's only option was to throw cigars and pipe tobacco over the edge or not.

Second, the FDA compounded its legal error by declining to exercise the authority it knew it had: The Final Rule could have, for example, allowed cigars and pipe tobacco to go through the substantial equivalence process in broad groups, greatly easing the burden of comparing them to a 2007 product. The agency arbitrarily rejected an alternative that would have saved the industry hundreds of millions of dollars, while still protecting the public health.

Third, the FDA denied cigars and pipe tobacco the stay of enforcement provided to cigarettes and smokeless tobacco while substantial equivalence applications were pending. For cigar and pipe tobacco products, if the FDA has not completed its review and declared them substantially equivalent to a 2007 product within at most 30 months after the effective date of the Deeming Rule, they must be pulled from the market. The FDA will never meet this deadline; similar cigarette applications have been pending for more than a half-decade. This is yet another example of the agency treating cigars and pipe tobacco more harshly than the cigarettes and smokeless tobacco for which Congress demanded immediate regulation.

Fourth, the agency rejected a less burdensome regulatory option it proposed in the first instance, exempting "premium cigars" from the Rule. Premium cigars are expensive and unused by minors. A recent FDA-funded study found *no* statistically significant youth use of premium cigars on any frequent basis. Tragically, the massive costs of the Rule on premium cigar manufacturers are inversely proportional to underaged premium cigar use: Premium cigars have

vast variety, turning on location, weather, and other factors. They are specialty products, hand-crafted by family-owned businesses through centuries-old artisan practices. There is no evidence in the record—none—that variations in premium cigars present any public health threat. The massive cost of running each premium cigar product through premarket review, without even identifying what the agency expects to detect, is the height of arbitrary and capricious rulemaking.

Fifth, the FDA simultaneously published a rule establishing "user fees" meant to fund the regulation of the cigars, pipe tobacco, and e-cigarettes the Deeming Rule reaches. *See generally* Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28,707 (May 10, 2016) ("User Fee Rule"). But the FDA imposed no fees on e-cigarettes, leaving other tobacco product manufacturers to pay for the massive task of e-cigarette regulation. This is not a "user fee" at all, but a tax meant to fund the regulation of industries. The User Fee Rule violates the Act and any conception of fairness.

Sixth, the FDA cavalierly fumbled its cost–benefit analysis of the Deeming Rule. The FDA's error was hardly for lack of warning: The D.C. Circuit has invalidated rule after rule for guesswork in evaluating costs and benefits and declining to compile available data. *See, e.g.*, *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011). Here, the FDA conceded that its Rule would shutter hundreds of small businesses in the cigar and pipe tobacco industries unable to absorb the costs of compliance, but claimed offsetting but unquantifiable public health benefits. On numerous occasions, the agency acknowledged it had not done necessary research to show health benefits but promised to do so in the future after the industry had borne all of the costs. Its analysis was arbitrary and capricious.

Seventh, the FDA imposed a new health warning scheme on cigars and pipe tobacco in violation of the First Amendment, the Act, and the Administrative Procedure Act (the "APA"). Most of the cigar industry currently puts health warnings on their packages and in advertising, pursuant to a Federal Trade Commission consent decree. The FDA did not materially change the content of the warnings, but it made them dramatically larger, to cover 30% of two panels of a cigar box and 20% of any advertisement, thereby crowding out and restricting manufacturers' ability to communicate with consumers. The agency never explained why the FTC warnings were inadequate and never claimed the larger warnings would reduce cigar use. But that is precisely the type of finding the Constitution requires—specifically, that a restriction of speech or a compelled disclosure *would* decrease *underaged* tobacco use. Congress knew this and responsibly demanded these types of agency findings before requiring new health warnings. *See* FD&C Act § 906(d)(1)-(2), 21 U.S.C. § 387f(d)(1)-(2).

Eighth, the agency required local pipe tobacco retailers, who blend FDA-approved finished pipe tobacco products at the request of their customers, to register with the FDA as "manufacturers." The FDA did so as an afterthought to regulating retailers who mix e-cigarette liquids, which of course might create some dangerous chemical reaction. Pipe tobacco has been blended by retailers for centuries, and there is no evidence in the record that two pipe tobacco products together are any more concerning than each apart. The FDA manipulates the Act's text to achieve this result, and the APA does not permit lumping these two different industries together, without explanation.

Ninth, the FDA threw a grandfather's traditional wooden pipe into the premarket review scheme, by concluding that "pipes" are "components" of a tobacco product. But the term "components" clearly refers to ingredients of and additives to tobacco products, not reusable

vessels (made without any tobacco constituents) for holding tobacco while it is being smoked. The small businesses manufacturing pipes today will never be able to shoulder the expense of FDA regulation, including premarket review. Here, the agency is destroying an entire industry, without ever bothering to identify how pipe variations are affecting the public health. Neither the Act nor the APA permits the agency's casual approach.

The Deeming Rule and User Fee Rule are invalid and must be vacated as arbitrary, capricious, and contrary to the Act and the Constitution.

BACKGROUND

I. PLAINTIFF ORGANIZATIONS

Plaintiff Cigar Association of America, Inc. ("CAA") is a non-profit trade association representing cigar manufacturers, importers, distributors, and major suppliers to the industry. CAA has members from all sectors of the industry, including manufacturers of handmade premium cigars and producers of machine-made small cigars.

Plaintiff International Premium Cigar and Pipe Retailers Association ("IPCPR") is a non-profit trade association representing premium cigar and tobacco retail shops, including many family-owned and operated small businesses, located throughout the United States and abroad. IPCPR is a "small organization" within the meaning of the Regulatory Flexibility Act ("RFA"), and IPCPR's members are "small businesses" for purposes of the RFA. 5 U.S.C. § 601(3), (4).

Plaintiff Cigar Rights of America ("CRA") is a non-profit association representing premium cigar manufacturers and consumers in the United States. CRA members include diverse artisan producers of handmade premium cigars and other members from across the supply chain—distributors, growers, mail-order houses, and logistics and associated supporting enterprises, among others—as well as consumers of premium cigars.

Plaintiffs CAA, IPCPR, and CRA have a vital interest in ensuring that any regulation of cigars, pipes, and pipe tobacco is consistent with statutory and constitutional requirements. Plaintiffs have standing to bring this suit because (a) their members would otherwise have standing to sue in their own right; (b) the interests they seek to protect are germane to the organizations' purposes; and (c) neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit. *See, e.g., United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552–53 (1996).

II. CONGRESS ENACTS THE TOBACCO CONTROL ACT TO COMBAT PRODUCT MANIPULATION AND MARKETING TO YOUTH

In 1996, the FDA promulgated a regulation seeking to reduce or eliminate addiction to cigarettes and smokeless tobacco by "preventing children and adolescents from starting to use tobacco." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). A group of tobacco manufacturers, retailers, and advertisers filed suit challenging the FDA's jurisdiction, and the Supreme Court held that the FDA lacked authority to regulate these products under the Food, Drug, and Cosmetic Act ("FD&C Act"). *Brown & Williamson*, 529 U.S. at 161.

Thereafter, Congress passed the Family Smoking Prevention and Tobacco Control Act, which amended the FD&C Act to impose restrictions on cigarettes, smokeless tobacco, and "roll-your-own" tobacco. The Act also authorized the FDA to regulate other tobacco products by promulgating a regulation to "deem" such products subject to the requirements of the TCA. *See generally* Pub. L. No. 111–31, 123 Stat. 1776, 1776–1852 (2009) (codified at 21 U.S.C. §§ 387–387u). The TCA's explicit purposes were, among other things:

> (2) 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 and dependence on tobacco; [and] . . .
>
> (7) 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[.]

TCA § 3, 123 Stat. at 1781–82.[1]

These statements of purpose followed a lengthy recitation of legislative findings accompanying the statute primarily focused on cigarettes and underage tobacco use. *See id.* § 2, 123 Stat. at 1776–81.[2] The findings never mention cigars or pipe tobacco. In the Act, Congress incorporated the substance of the 1996 FDA regulations that were at issue in *Brown & Williamson*, stating they "will 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." *See id.* § 2(31), 123 Stat. at 1779. The Act also highlighted judicial findings regarding alleged abuses by the cigarette industry, including that: "the major United States cigarette companies continue to target and market to youth"; "the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998"; and "the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain

[1] Citations to the TCA herein are limited to sections 1–6 of the Act (TCA §§ 1–6), which were not codified in the United States Code but can be found in the Statutes at Large (123 Stat. at 1776–83). Other citations are to the applicable sections of the FD&C Act (FD&C Act §§ 901–920) and to the sections of the United States Code where those provisions are codified (21 U.S.C. §§ 387–387u).

[2] Nearly half of the legislative findings (21 out of 49) address youth and adolescents, in terms of either use or marketing of tobacco. *See* TCA § 2, 123 Stat. at 1776–81. Many others (e.g., findings 16, 38, 39, and 49) are directed specifically to the cigarette industry. *See id.*, 123 Stat. at 1778, 1780, 1781.

addiction while also concealing much of their nicotine-related research." *See id.* § 2(47)–(49), 123 Stat. at 1781.

Enactment of the Act was grounded in significant concerns regarding the cigarette industry's history of product manipulation and youth marketing schemes and other closely related tobacco products. Accordingly, the *only* products that Congress mandated for immediate regulation under the Act were cigarettes, roll-your-own tobacco, and smokeless tobacco (the "Originally Regulated Products"). *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). Regulation of other tobacco products was left to the FDA, subject to the APA. *See id.*

III. THE STATUTORY PREMARKET REVIEW SCHEME

The Act established a detailed premarket review scheme for cigarettes, smokeless tobacco, and roll-your-own tobacco. With certain exceptions, such products that were not on the market as of February 15, 2007 (the "predicate date") cannot be marketed until a premarket application is submitted to, and a marketing authorization order is received from, the FDA. *See id.* § 910(a), 21 U.S.C. § 387j(a). A marketing authorization order is not required if: (a) a manufacturer submits a substantial equivalence report to the FDA under section 905(j) of the FD&C Act and obtains an order under section 910(a)(2) finding that the new tobacco product is "substantially equivalent" to a tobacco product commercially marketed in the United States as of February 15, 2007, or to a tobacco product that the FDA determined was substantially equivalent to a tobacco product commercially marketed as of February 15, 2007 and in compliance with the requirements of the FD&C Act (such products are commonly referred to as the "predicate product"); or (b) a tobacco product is exempt from the substantial equivalence process because it makes only an immaterial modification to an already approved product. *Id.* §§ 905(j), 910(a)(2)(A), 21 U.S.C. §§ 387e(j), 387j(a)(2)(A).

A "substantially equivalent" tobacco product is a product that (i) "has the same characteristics as the predicate tobacco product"; or (ii) "has different characteristics," but the information and/or data submitted to the FDA "demonstrates that it is not appropriate to regulate the product [through the premarket review process] because the product does not raise different questions of public health." *Id.* § 910(a)(3)(A), 21 U.S.C. § 387j(a)(3)(A).[3] The substantial equivalence process itself requires extensive and expensive testing and submissions, and the availability of predicate products is central to the substantial equivalence showing. Congress understood the process would take time, so it permitted cigarettes and smokeless tobacco that were introduced in the 21 months after the Act's enactment to continue to be sold until the FDA completed its review of the substantial equivalence applications submitted for them. *Id.* § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(B).

The Act's ongoing substantial equivalence process from the inception of the Act was intended to update predicate tobacco products and is critical to the continued function of the Act's substantial equivalence provisions. That is because, with an ongoing process, a manufacturer could compare a new product to an earlier substantially equivalent version that is reasonably proximate in time to the proposed marketing date for the new tobacco product. This mechanism becomes practically unavailable when regulation of a product class does not begin until ten years after the predicate date.[4]

[3] The term "characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." FD&C Act § 910(a)(3)(B), 21 U.S.C. § 387j(a)(3)(B).

[4] The TCA's substantial equivalence process, including its specification of predicate products, was derived from the FD&C Act's device provisions. Those provisions were updated in the Safe Medical Devices Act of 1990 and reflected fourteen years of agency practice that included the ability to update predicates with devices found to be substantially equivalent. *See* H.R. Rep. No. 101-808, at 25 (1990) (permitting predicates to be updated will cause "the standard for safety and effectiveness in a determination of substantial equivalence [to] evolve slowly as the prevailing

It is difficult, if not impossible, to show that a new product is substantially equivalent to a predicate product if the predicate product is so remote from the present that the company cannot gather the data required by the FDA, through testing or otherwise. For cigarettes and smokeless tobacco, FDA requires that substantial equivalence reports include, among other things, "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product" and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product." *Id.* § 910(b)(1), 21 U.S.C. § 387j(b)(1).

In addition to the premarket review process, the FD&C Act imposes other regulatory burdens on manufacturers and retailers of cigarettes, smokeless tobacco, and roll-your-own tobacco products. Among other things, the statute: (a) requires manufacturers to submit detailed health information on each tobacco product (including lists of ingredients and harmful or potentially harmful constituents ("HPHCs"), descriptions of the form and delivery of nicotine, and documents relating to the health and toxicological effects of products, ingredients, and additives) to the FDA; (b) mandates registration and biannual inspection of manufacturing facilities; and (c) directs manufacturers to maintain extensive records and reports. *Id.* §§ 904(a), 905(b)–(d), (g), 909(a), 21 U.S.C. §§ 387d(a), 387e(b)–(d), (g), 387i(a). The Act also authorizes the FDA to require warning labels on tobacco products, to impose restrictions on the sale and distribution of tobacco products, to regulate manufacturing methods, to prescribe wide-ranging tobacco product standards, and to issue record-keeping regulations directed at manufacturers,

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level on the market changes"); *see also* U.S. Food & Drug Admin., *Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3* at 2 (June 30, 1986) ("[T]he Center requires submitters to provide information that compares the new device to a marketed device of a similar type, regardless of whether this marketed device was marketed before or after enactment of the Amendments . . . .").

importers, and retailers of tobacco products. *Id.* §§ 903(a)–(b), 906(d)–(e), 907(a)(3)–(4), 920(b), 21 U.S.C. §§ 387c(a)–(b), 387f(d)–(e), 387g(a)(3)–(4), 387t(b).

IV. THE FDA "DEEMS" ALL CIGARS AND PIPE TOBACCO SUBJECT TO THE REGULATORY SCHEME CONGRESS CREATED FOR IMMEDIATE APPLICATION TO CIGARETTES AND SMOKELESS TOBACCO

On April 25, 2014, the FDA issued a proposed rule deeming cigars, pipe tobacco, and e-cigarettes subject to the TCA. *See generally* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142 (Apr. 25, 2014). From the beginning, the FDA acknowledged that cigars and pipe tobacco were an awkward fit with Congress's scheme for regulating cigarettes and smokeless tobacco. Specifically, the FDA admitted doubt that cigar and pipe tobacco "manufacturers would in fact be able to use the SE [substantial equivalence] pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate." *Id.* at 23,176. The FDA sought comments on whether, among other things: (1) it should "consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the SE pathway"; (2) if it did "establish a compliance policy or an expedited review process, . . . the policy or expedited process [should] apply to all proposed deemed products or only to certain categories of products, such as based on their relative impact on public health"; and (3) there are "unique challenges faced by small manufacturers of proposed deemed tobacco products" and how they should be addressed. *Id.*

The FDA simultaneously issued a Preliminary Regulatory Impact Analysis ("PRIA"), in which it announced that it would not carry out a meaningful cost–benefit analysis any time before the rule went final. Instead, the agency said it would worry about that later. It suggested it would conduct a so-called "retrospective review" after implementing the final rule, a concept

nowhere contemplated in Executive Order 12,866. *See* AR010643; *see also* Exec. Order No. 12,866 § 1(b)(6), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

The FDA sought comments on two "options" for what tobacco products it would now regulate. "Option 1" would "deem" all cigars subject to the Act. "Option 2" would exempt "premium cigars" from any regulation. 79 Fed. Reg. at 23,150. The proposed rule defined "premium cigars" by distinguishing "covered" and "non-covered" cigars. A "non-covered" cigar was a cigar that:

> (1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.

Id.

Plaintiffs and numerous other parties submitted detailed comments on the proposed rule. They explained the significant burdens that would be imposed on their businesses if the TCA were applied to their products and the obvious inequities and impossibilities presented by the proposed February 15, 2007 predicate date for grandfathering and substantial equivalence given the seven years that had passed since enactment of the TCA.[5] Plaintiffs also urged the agency to adopt "Option 2," but with certain modifications to the definition of premium cigar.[6]

The FDA largely rejected the comments received and finalized a rule almost identical to the one it had proposed. On May 10, 2016, the agency promulgated a Final Rule imposing the entire weight of the Act's regulatory scheme on all cigars, pipe tobacco, and e-cigarettes (the

[5] *See, e.g.*, AR129900–09; AR130348–50, AR130354–56; AR159757–64.

[6] *See* AR129915–24; AR130345–48; AR134763–67.

"Newly Deemed Products"). No exemption was made for premium cigar manufacturers. *See generally* 81 Fed. Reg. at 28,974–29,106.[7] The FDA concluded that it lacked authority to make changes to much of the regulatory scheme Congress crafted for cigarette and smokeless tobacco, applying it to cigars and pipe tobacco in rote fashion. That included disclaiming discretion to modify the predicate date, requiring showings of substantial equivalence between Newly Deemed Products and products on the market as of February 15, 2007. Cigar and pipe tobacco manufacturers now have to look back more than *nine years*, nearly four times longer than the two-and-a-half years cigarettes and smokeless tobacco had to cover. *Id.* at 28,993. This requirement not only makes it extraordinarily difficult to find predicates for cigars and pipe tobacco due to the changing characteristics of products made from agricultural components, but also effectively eliminates the prospect of relying on more current substantially equivalent cigars and pipe tobacco as predicates.

The Rule created other arbitrary inequities between the cigarettes and smokeless tobacco products for which Congress directed immediate regulation and the cigars and pipe tobacco the regulation of which Congress left to the FDA's discretion. Foremost was the forbearance of enforcement during the pendency of FDA applications. Cigarettes and smokeless tobacco for which a substantial equivalence report was filed by March 22, 2011, were allowed to remain on the market unless and until the FDA rejected the product's application. FD&C Act § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(B). Cigar and pipe tobacco manufacturers, in contrast, were provided set forbearance periods—24 months for substantial equivalence exemption requests, 30 months for substantial equivalence reports, and 36 months for premarket applications. 81 Fed. Reg. at 29,011. After these periods expire—even if the FDA has taken no

[7] Tobacco pipes were also subject to regulation as "components" of pipe tobacco. *See* 81 Fed. Reg. at 29,042.

action—manufacturers will have to pull these products from the market. *See id.* ("Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement."). The rule leaves cigar and pipe tobacco manufacturers at the mercy of the FDA's speed in performing its review of their products. The FDA's history with cigarettes and smokeless tobacco applications leaves little hope that the FDA will complete review within these time limits.[8]

The FDA simultaneously promulgated a separate rule that imposed user fees on some, but not all, newly deemed products. *See generally* 81 Fed. Reg. at 28,707–16. To fund regulation under the TCA, Congress authorized the FDA to prescribe "user fees" to be paid by regulated entities. FD&C Act § 919, 21 U.S.C. § 387s. Congress provided an initial assessment formula that included those tobacco products that existed on the market at the time of the statute's enactment. *See id.* § 919(b)(2)(B)(i), 21 U.S.C. § 387s(b)(2)(B)(i). The FDA declined to impose user fees on newly deemed products that were not specifically identified in Congress's initial allocation formula. Although the FDA acknowledged that this selective imposition of user fees would result in "free riders," the agency stated that it lacked authority under the TCA to impose user fees on newly regulated tobacco products not identified in Congress's initial formula. 81 Fed. Reg. at 28,709–12.

[8] The FDA has received a total of 6,589 Product Applications—premarket applications, regular and provisional substantial equivalence reports, exemptions, and modified risk submissions—since program inception, and only 2,819 have received Final Actions, representing a 42.8% completion rate. *Cumulative Number of Product Applications Received Since Program Inception*, U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-since-Program-Inception (last updated Sept. 30, 2016). The FDA's statement that it *may*, on a case-by-case basis, extend the forbearance periods therefore provides little comfort to manufacturers. 81 Fed. Reg. at 29,012.

V. THE RULE THREATENS TO RUIN THE CIGAR AND PIPE TOBACCO INDUSTRIES

The Deeming Rule imposes extraordinary and disproportionate burdens on the cigar and pipe tobacco industries. This crushing regulatory scheme is all but certain to compel many manufacturers and retailers to close their doors or radically change the way they do business. What the regulation ignored is the vast diversity of products in the cigar and pipe tobacco industries, with differences of taste and aesthetics that do not, in and of themselves, affect the health risks of such products.[9] By the FDA's own estimates, the number of unique cigar and pipe tobacco products dwarfs the varieties of cigarettes.[10] This is so even though the cigar industry is roughly eight percent the size of the cigarette industry, and the premium cigar industry represent less than 0.1 percent of the U.S. tobacco market. AR129899; AR130336; *see also* AR129595. The premium cigar industry, for instance, manufactures significant numbers of limited run products, based on the quality and characteristics of tobacco leaf harvested, varying further based on season, location, and weather. Given the nearly ten years that have passed since the predicate date, it will be nearly impossible to find predicate products for today's cigar products to support a substantial equivalence report. Manufacturers therefore face a Hobson's choice of either preparing expensive premarket applications for each of their numerous and diverse products, or ceasing to offer many of their products altogether.[11] Even with substantial equivalence availability, each product will be subject to laborious paperwork and testing. The result will be dramatically narrowed product offerings.

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[9] *See, e.g.*, AR129897, AR129899–900; AR130337, AR130349–50; AR130239; AR081246–47; *see also* 81 Fed. Reg. at 29,079 (discussing premium cigars).

[10] AR023989 (estimating 7,500 cigar UPCs, 1,100 pipe tobacco UPCs, and 4,610 pipe UPCs). These numbers are likely *understated* for cigars, which industry estimates place no lower than 8,000 or 10,000, and potentially as high as 20,000. *See* AR129900; AR130349; AR159690.

[11] *See, e.g.*, AR129901, AR129920; AR129613–14.

The crushing effect of the rule will be felt by the cigar industry generally, and particularly in the premium cigar and pipe tobacco industries, where product variation reigns supreme.[12] These same features of the cigar and pipe tobacco markets will render the ingredient-listing and HPHC-testing mandates exorbitantly costly for industry participants, in part because each such manufacturer must test a vastly greater number of products at significantly lower gross revenues per product than the Originally Regulated Products.[13] The agency's required warning labels also place a disproportionate burden on cigar and pipe tobacco manufacturers, who must prepare and place (at significant expense) a large and obtrusive warning label on each unique product, regardless of the distinctive packaging to which both consumers and sellers assign value.[14] These costs lack any meaningful parallel in the market for cigarettes, which are homogenized and mass-produced, capable of testing under existing procedures, and packaged uniformly and in bulk.[15] Small manufacturers, including premium cigar manufacturers, are unlikely to survive the rule. The cigar industry will consolidate, leaving behind only those large corporate entities who can absorb the costs of compliance.

ARGUMENT

I. STANDARD OF REVIEW

Summary judgment under the APA "serves as the mechanism for deciding, as a matter of law, whether [an] agency action is supported by the administrative record and otherwise

[12] In the premium cigar market, consumers expect a constant stream of new and innovative products. *See* AR129897; AR130337, AR130349; AR129596; AR159690. Pipes are characterized by vast diversity as well. *See, e.g.*, AR150694 (noting that "[t]here are innumerable variations of pipes"); AR161116 (citing "hundreds of styles" of pipes). In the pipe tobacco market, consumers desire consistency in taste, which requires the use of different blends, casings, and flavorings. AR130239.

[13] *See, e.g.*, AR130352; AR129614–15; AR159714–17; AR130245.

[14] *See, e.g.*, AR129929–30; AR130350–52; AR134770; AR129615–16.

[15] *See* AR129896, AR129899; AR130337; AR129614–15; AR159689, AR159716.

consistent with the APA standard of review." *All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 118 (D.D.C. 2011). The APA demands that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In assessing agency action under the APA, "the Court must engage in a 'thorough, probing, in-depth review'" to determine "whether the agenc[y] ha[s] 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action.'" *Individual Reference Servs. Grp., Inc. v. FTC*, 145 F. Supp. 2d 6, 25 (D.D.C. 2001). The court "considers whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied have some basis in the record, and whether the agency considered the relevant factors." *Id.* Counsel's "*post hoc* rationalizations" will not do; "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

When the constitutionality of an agency's action is challenged, the court "must (like any appellate tribunal) determine for itself whether the agency based its decision on the appropriate constitutional standard." *United Space All., LLC v. Solis*, 824 F. Supp. 2d 68, 78 (D.D.C. 2011). The court's role is the same whether the suit proceeds under the APA or directly under the Constitution. *All. for Nat. Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 12 n.10 (D.D.C. 2011). "'[A] reviewing court owes no deference to the agency's pronouncement on a constitutional question,' and must instead make 'an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making.'" *Poett v. United States*, 657 F. Supp. 2d 230, 241 (D.D.C. 2009). This sort of searching "'[i]ndependent judicial judgment is especially appropriate in the First Amendment area.'" *Id.*

II. THE FDA'S REGULATION SUBJECTING CIGARS AND PIPE TOBACCO TO ALL ASPECTS OF THE PREMARKET REVIEW SCHEME CONGRESS APPLIED TO CIGARETTES AND SMOKELESS TOBACCO, WHILE DENYING THEM ACCESS TO SUBSTANTIAL EQUIVALENCE, IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW

The FDA imposed a premarket review scheme Congress intended for immediate regulation of cigarette and smokeless tobacco on all cigars and pipe tobacco, and it did so in a way that regulated cigars and pipe tobacco *more harshly* than cigarettes and smokeless tobacco.[16] The agency concluded that this result was *statutorily required* once it "deemed" cigars and pipe tobacco subject to the Act, yet supplied no explanation for why such regulation is justified for cigars and pipe tobacco, through scientific evidence or otherwise. As a result of the agency's mistaken interpretation of the statute, cigar and pipe tobacco manufacturers are subjected to a premarket review process more burdensome than the cigarettes and smokeless tobacco products Congress believed required immediate regulation to protect public health. The agency's regulatory approach is arbitrary, capricious, and contrary to law. Its rule cannot stand.

The FDA concluded that all cigars and pipe tobacco should be regulated and that it had only one choice to do so: Using its Section 901 authority to "deem" those products subject to the Act. *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). According to the agency, "deeming" a tobacco product "automatically" subjects that product to "all statutory provisions that apply to all tobacco products" covered by the Act. 81 Fed. Reg. at 29,000; *see also, e.g.*, *id.* at 29,034. The FDA then distinguished the Act's "automatic provisions" from what it calls "additional provisions" of the Act that the FDA could apply to cigars and pipe tobacco as it wishes. *Id.* at 28,976, 28,980. According to the FDA, once it deems a tobacco product subject to the TCA, it must apply the "automatic" provisions without regard for whether doing so would lead to results

[16] Because of its erroneous inclusion of tobacco pipes as "components," tobacco pipes also are subject to this process. *See infra* Section XI.

that Congress could not possibly have intended, such as the destruction of large segments of the market for the products newly subject to regulation. *Id.* at 29,000.

This agency interpretation leads to absurd results, the greatest of which is the FDA's retention of the February 15, 2007 predicate date. The predicate date is at the heart of the premarket review process and is determinative of the regulatory pathway for non-exempt tobacco products. That date was designed for the cigarette and smokeless tobacco products Congress regulated in 2009, but makes no sense for the cigars and pipe tobacco products first regulated in 2016. The date Congress chose for cigarettes and smokeless tobacco reflects *proximity* to the initiation of regulation, and would facilitate substantial equivalence comparisons between tobacco products marketed by and after that date. Substantially equivalent "new" products could be marketed without the premarket review that Congress envisioned would enable the FDA "to obtain needed data on the risks of *novel* tobacco products, and to assure that such products do not introduce more risks than *conventional* tobacco products." S. Rep. No. 105-180, at 23 (1998) (emphases added). These "new" substantially equivalent products could serve as predicates for still further product development through the substantial equivalence process.

But for cigars and pipe tobacco, if the FDA's rule were allowed to stand, a predicate date from nearly a decade ago would result in undermining the ability to differentiate "novel" products from "conventional" products and effectively preclude cigar and pipe tobacco manufacturers from marketing products created after 2007. Under the Rule, cigar and pipe tobacco manufacturers must compare today's products to, and amass extensive data about, those marketed in 2007 to have any hope of establishing substantial equivalence and avoiding a separate premarket tobacco product application. *See* FD&C Act §§ 905(j), 910(a)(3)–(4), 21 U.S.C. §§ 387e(j), 387j(a)(3)–(4).

That is practically an insurmountable burden, as data and samples for products in the marketplace nearly a decade ago have long since disappeared. The result of the FDA's wooden predicate date is that virtually *every* cigar and pipe tobacco product will have to go through the full premarket review process, a crushing expense Congress largely spared the cigarette industry by choosing a predicate date for cigarettes just two years before the initiation of regulation. *See, e.g.*, AR129901 (the 2007 predicate date "would result in a paucity of predicates available for comparisons, . . . creating a situation in which substantial equivalence showings would be enormously difficult, if not impossible"); AR023949 ("premarket tobacco applications are more expensive, on average, than substantial equivalence or SE exemptions").

This unnecessary and unjustified burden is exacerbated by the substantially greater number of cigar and pipe tobacco products compared to the cigarette and smokeless tobacco industries. Although some cigars and pipe tobacco are mass-produced, premium cigars, by the FDA's own definition, are never mass produced. *See* 79 Fed. Reg. at 23,150 (defining premium cigars to be "made by combining manually the wrapper, filler, and binder"). They differ according to the tastes of the master blender and the conditions of the component crops. Special edition and seasonal blends comprise a substantial portion of the market and account for a considerable share of the average tobacconist's sales.[17] Pipe tobacco manufacturers and retailers also often make blending changes to provide variety or to preserve the pipe tobacco's character.[18]

In addition, weather and local growing conditions have a much greater impact on cigar manufacturing than cigarette manufacturing, which drive manufacturers to blend tobaccos to

[17] AR129896, AR129899–900, AR129915; AR130337, AR130349, AR130352; AR129614; AR130239; AR081246.

[18] AR130239, AR130244; AR081246–47.

maintain a cigar's identity and taste from year to year.[19] The artisanal process of manufacturing a premium cigar takes three to five years from the time the tobacco seed is planted.[20] Whereas four manufacturers control more than 90% of the cigarette market, there are hundreds of cigar manufacturers, many of whom may have 50 to 100 stock-keeping units ("SKUs").[21] Just looking at premium cigars, there are between 10,000 and 20,000 unique SKUs in the United States,[22] and that number is a fraction of the total number of cigar SKUs available in this country. By contrast, cigarettes are mass-produced by machines capable of generating millions of identical products per hour, and the FDA has estimated that there are approximately 5,300 active UPCs for cigarettes, smokeless tobacco, cigarette or smoking tobacco, and cigarette paper *together*.[23]

Importantly, variations in cigar and pipe tobacco products are directed at flavor, taste, or aesthetics, rather than aimed at altering the health risks of such products.[24] Unlike cigarettes, there has been no claim that the cigar or pipe tobacco industries have manipulated ingredients and components to affect nicotine or tar levels. *Compare* TCA § 2(47)–(49), 123 Stat. at 1781. Nor is there any systematic history of introducing new cigar or pipe tobacco products with any alleged suggestion that they are healthier than others. The defining features of cigars and pipe tobacco—vast product diversity and comparatively slow and small-scale manufacturing—will make the premarket tobacco product application and review process prohibitively expensive.

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[19] AR129899; AR159688–89; AR157821 .

[20] AR129899; AR130377; *see also* AR129613 (describing the unique manufacturing process of premium cigars); AR159688–89 (same); AR159757–58 (same).

[21] AR130336–37.

[22] *See* AR130349; AR159690.

[23] *See* AR159689; AR010618–19.

[24] *See* AR129899, AR129905–06; AR130349; AR159759; AR159689; AR130239; AR081246–47.

For this reason, the availability of the substantial equivalence process is of vital importance to the industry. Yet the FDA's insistence on the February 15, 2007 predicate date ignores the logic and purpose behind the Act, including that Act's prohibition on banning segments of the tobacco industry, and largely forecloses relief for cigars and pipe tobacco from the TCA's prohibitively expensive premarket review provisions. *See* FD&C Act § 907(d)(3), 21 U.S.C. § 387g(d)(3) (regulation banning all cigars and pipe tobacco is "prohibited"). Indeed, the FDA's imposition of the 2007 predicate date effectively deprives cigar and pipe tobacco manufacturers of the ability to update their predicate products in the way that cigarettes and smokeless tobacco have been able to do as their products have evolved over time.

This interpretation of the Act as requiring it to regulate cigars and pipe tobacco more harshly than Originally Regulated Products stands the statutory structure on its head. Congress intended that the substantial equivalence pathway would be available to "all tobacco products," not just cigarettes, smokeless tobacco, and roll-your-own tobacco. 81 Fed. Reg. at 28,993. Denying cigars and pipe tobacco the same access to this pathway as that enjoyed by the Originally Regulated Products is contrary to the Act's structure and represents a textbook case of arbitrary and capricious treatment. *See Burlington N. & S.F. Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld.").

This outcome—a premarket review process more burdensome than the one for cigarettes and smokeless tobacco, weighed down by a predicate date ten years old—was far from necessary or required by statute. Nothing in the Act, textual or otherwise, indicates that Congress intended to impose a more burdensome regulatory structure on newly deemed products. Rather, Congress

gave the agency the discretionary authority to determine through the rulemaking process *whether* and *how* to regulate cigars and pipe tobacco in Section 901: "This chapter shall apply to . . . any other tobacco products that the Secretary *by regulation* deems to be subject to this chapter." FD&C Act § 901(b), 21 U.S.C. § 387a(b) (emphasis added). Congress's reference to the agency acting "by regulation" clearly connotes the discretion to calibrate a regulatory scheme for the tobacco products the agency later chooses to regulate. *See Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 386 (D.D.C. 1991) (statute mandating that the effectiveness of a device be determined "in accordance with regulations promulgated by the Secretary" conferred "sweeping discretion" on the agency).

Other provisions reinforce the FDA's discretion to make changes to the regulatory scheme Congress designed for immediate application to cigarette and smokeless tobacco when regulating other products. The Secretary's primary authority in promulgating regulations under the FD&C Act is rooted in Section 701 of the statute, which vests the Secretary with "authority to promulgate regulations for the *efficient* enforcement" of the Act. FD&C Act § 701(a), 21 U.S.C. § 371(a) (emphasis added). Likewise, Congress granted the FDA "*flexible* enforcement authority" and directed the agency to "impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(4), (8), 123 Stat. at 1782 (emphases added). At a minimum, these provisions make clear that rote application of the February 2007 predicate date in a way that disfavors cigars or pipe tobacco is in no manner "compelled" by the TCA itself.

Importantly, Congress chose not to regulate cigars and pipe tobacco in the first instance. That is because Congress was focused on cigarettes and smokeless tobacco, and did not mandate whether or how cigars and pipe tobacco should be regulated. *See* FD&C Act § 901(b), 21 U.S.C. § 387a(b). Neither cigars nor pipe tobacco are mentioned in the committee reports on the Act.

See H.R. Rep. No. 111-145 (2009); H.R. Rep. No. 111-72 (2009); H.R. Rep. No. 111-58, pts. 1–2 (2009); H.R. Rep. No. 110-762 (2008). Similarly, hearings on the Act contain no discussion of the proper level of regulation for cigars and pipe tobacco. Nor do they reference these products as problems for youth initiation or access, deceptive marketing as healthier alternatives, or the manipulation of nicotine or other constituents, in the course of their long appraisal of cigarette public health problems.[25] And the only references to cigars or pipe tobacco in the Congressional Record appear in the floor remarks of a single Representative who observed, on three occasions, that cigars and pipe tobacco are beyond the scope of the legislation. 155 Cong. Rec. H6626, H6654 (daily ed. June 12, 2009) (remarks of Rep. Steve Buyer); 155 Cong. Rec. H3802 (daily ed. Mar. 24, 2009) (remarks of Rep. Steve Buyer).

The structure of the Act, and the FDA's effort to classify some of its provisions as "automatic" and some as "additional" or "discretionary," also demonstrate that the FDA retained the discretion to calibrate aspects of the cigarette and smokeless tobacco regulatory scheme when extending it to cigars and pipe tobacco. Take, for example, the agency's treatment of Section 904, which requires tobacco product manufacturers to submit lists of ingredients and constituents to the FDA by certain deadlines. FD&C Act § 904(a)(1)–(4), 21 U.S.C. § 387d(a)(1)–(4). The agency labels Section 904 as "automatic," but goes on to revise statutory dates therein, which had already passed, as applied to cigars and pipe tobacco. 81 Fed. Reg. at 28,976, 29,006. The FDA has offered no explanation for why it may adjust an "automatic" statutory provision like Section 904 because of the passage of time, but is forbidden to modify the 2007 predicate date

[25] *See* The Family Smoking Prevention and Tobacco Control Act: Hearing Before the Subcomm. on Health of the Comm. on Energy & Commerce on H.R. 1108, 110th Cong. (2007); The Need for FDA Regulation of Tobacco: Hearing of the Comm. on Health, Educ., Labor, & Pensions on Examining S. 625, to Protect the Public Health by Providing the Food and Drug Administration with Certain Authority to Regulate Tobacco Products, 110th Cong. (2007).

that is equally absurd when applied to cigars and pipe tobacco. Indeed, the impossibility of applying all statutory provisions to products first regulated years in the future shows that Congress expected the agency to tailor the predicate date, as well as aspects of the regulatory scheme, to the circumstances of the newly regulated industry and the timing of the regulation.

Importantly, the FDA is not entitled to any deference in its incorrect interpretation of the Act as depriving it of discretion. The law of this circuit is settled that "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan Bus Lines, Inc. v. FMCSA*, 471 F.3d 1350, 1354 (D.C. Cir. 2006). Indeed, when an agency incorrectly concludes that a statute unambiguously compels a particular regulatory outcome, its action cannot stand—regardless of whether it could have achieved the same end through proper regulation. *See Arizona v. Thompson*, 281 F.3d 248, 259 (D.C. Cir. 2002). Because of its erroneous interpretation of the statute, the agency passed by multiple options for tailoring the regulatory scheme for cigars and pipe tobacco.

The proper remedy is to vacate the Deeming Rule for the agency to exercise its full statutory discretion and, in doing so to ensure that cigars and pipe tobacco at least are regulated no more harshly than the Originally Regulated Products. *See Int'l Swaps & Derivatives Ass'n v. CFTC*, 887 F. Supp. 2d 259, 283–84 (D.D.C. 2012) (vacating final rule where agency erroneously deemed statute unambiguous and therefore "failed to bring its expertise and experience to bear when interpreting the statute and offered no explanation for how its interpretation comported with the policy objectives of the Act"); *Humane Soc'y of U.S. v. Kempthorne*, 579 F. Supp. 2d 7, 20–21 (D.D.C. 2008) (vacating final rule and instructing agency on remand to, "[a]t a minimum, . . . explain how its interpretation of the statute conforms to the text, structure and legislative history of the [act]; how its interpretation is consistent with judicial

interpretations of the [act] (if there are any on point); and how its interpretation serves the [act's] myriad policy objectives").

III. THE RULE'S IMPOSITION OF PREMARKET REVIEW WITHOUT CLARIFYING THE SUBSTANTIAL EQUIVALENCE PATHWAY FOR CIGARS AND PIPE TOBACCO IS ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION

Even if the FDA were somehow required to implement all aspects of the premarket review scheme Congress applied to cigarettes and smokeless tobacco—including a nearly decade-old predicate date—the FDA has other authorities to tailor the scheme to the unique aspects of cigars and pipe tobacco. Foremost among them is the FDA's authority to provide rules governing its substantial equivalence determinations. *See* FD&C Act § 905(j)(1), 21 U.S.C. § 387e(j)(1).

For those products the FDA sought to deem, the FDA sought comments on whether and how it should clarify the application of substantial equivalence to those products in the Final Rule. Commenters answered and requested that the FDA couple any deeming rule with regulations facilitating substantial equivalence for cigars and pipe tobacco.[26] Rules governing the substantial equivalence process could have treated cigars in the same product family (those with the same type of tobacco blend, filler, and wrapper, but in different shapes and sizes) as substantially equivalent and limited premarket review to new product families, or could have adopted an alternative system for premium cigars where the manufacturer provides notice of a new product and asserts its substantial equivalence subject to an agency call for further information.[27]

[26] *See, e.g.*, AR161086, AR161090.

[27] *See* AR130345; AR157840 .

Any of these alternatives would have tempered, but not eliminated, the extraordinary burdens of pre-market review on a cigar and pipe tobacco industry with tens of thousands of products, varied in ways having nothing to do with public health. But the agency declined to clarify or modify the substantial equivalence procedure for cigars and pipe tobacco when it issued its Final Rule, saying only that it *might* later issue rules specific to cigars and pipe tobacco. 81 Fed. Reg. at 29,011–12. Recognizing that such rules were necessary, the agency has drafted a rule but not publicly released it. *See* Regulatory Agenda, 81 Fed. Reg. 94,742, 94,742, 94,745 (Dec. 23, 2016).[28] Cigars and pipe tobacco were even less fortunate than electronic cigarettes, for which the agency issued industry-specific guidance simultaneously with the Final Rule. 81 Fed. Reg. at 29,012; *see also* Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, 81 Fed. Reg. 28,781 (May 10, 2016).

Substantial equivalence applications are due on February 8, 2018. The industry is incurring the costs of preparing for that process—individual product by product—now. The FDA created a premarket review scheme—focused on comparing today's products to those on the market ten years ago—with burdens unrelated to advancing public health. If commenters propose a less burdensome scheme, equally effective at achieving the agency's goals, the agency must explain why it declines that option. *Del. Dep't of Nat'l Res. & Envtl. Control v. EPA*, 785 F.3d 1, 18 (D.C. Cir. 2015) ("Because EPA too cavalierly sidestepped its responsibility to address reasonable alternatives, its action was not rational and must, therefore, be set aside.");

[28] In 2011, the agency published answers to "frequently asked questions" regarding the substantial equivalence process and has revised it several times since. *See* Ctr. for Tobacco Prods., U.S. Food & Drug Admin., *Draft Guidance for Industry and FDA Staff – Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Sept. 2011); *see also* Ctr. for Tobacco Prods., U.S. Food & Drug Admin., *Guidance for Industry – Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)* at 20 (Dec. 2016). But that guidance makes no specific reference to cigars or pipe tobacco.

State Farm, 463 U.S. at 48 (agency arbitrarily failed to address alternative way of achieving statutory purpose). A promise of future rules, which now almost certainly will occur after the industry incurs all the costs of compliance with the Rule, does no good. Creating a regulatory mess—and promising a solution later, after the industry bears all of the costs—is the definition of capricious.

IV. THE FDA ARBITRARILY DENIED CIGARS AND PIPE TOBACCO THE SAME STAY OF ENFORCEMENT PENDING APPROVAL OF THEIR SUBSTANTIAL EQUIVALENCE APPLICATIONS PROVIDED TO CIGARETTES

The FDA permitted cigarettes and smokeless tobacco products to remain on the market until the FDA completed review of their substantial equivalence applications. *See* FD&C Act § 910(a)(2)(B), 21 U.S.C. § 387j(a)(2)(b). The FDA originally proposed a similar approach for cigars and pipe tobacco. *See* 79 Fed. Reg. at 23,175. Recognizing that it was "not certain that manufacturers would in fact be able to use the SE pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate," the agency even proposed expanding the cigarette stay of enforcement to the pendency of premarket approval applications. *Id.* at 23,176.

The Final Rule, however, radically changes course and declines to permit products to remain on the market while the FDA considers applications of any kind. Instead, cigar and pipe tobacco products may remain on the market only during the 18-month period between the effective date of the rule and the deadline for making substantial equivalence applications and then only for another 12 months while their applications are pending. Thereafter the products must be pulled from the market, even if the FDA has not made up its mind. 81 Fed. Reg. at 28,978, 29,010–11.

The agency provided no meaningful justification for this difference in treatment, much less the "reasoned analysis" courts require for changing a longstanding regulatory policy. *State*

Farm, 463 U.S. at 56–57; *see also Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014). The FDA says it is concerned about unreviewed cigars and pipe tobacco remaining on the market, with potential exposure to minors, while the FDA's decisionmaking process continues to grind. 81 Fed. Reg. at 29,014. But that is no distinction from cigarettes, many of which for years have remained on the market pending review and to which the underaged seek access in dramatically higher numbers. *See* Declaration of Cecil Reynolds ("Reynolds Decl.") ¶¶ 25, 30. To put it sharply, nothing in the Rule explains why cigars and pipe tobacco should be treated more harshly than cigarettes.

If anything, the facts over the last eight years have shifted more strongly in favor of forbearance throughout the pendency of cigar and pipe tobacco applications, because of the agency's now demonstrated inability to process those applications in any timely fashion. The agency still has not processed cigarette substantial equivalence applications filed six years ago; twelve months after application submission will not be nearly enough time for the agency to act. Of 6,589 product applications, only 2,819 have received final action.[29] This backlog will only get worse, given that the cigar and pipe tobacco products have much higher numbers of SKUs than cigarettes and smokeless tobacco. The absence of forbearance is flatly contrary to one of the primary purposes of the TCA: "[T]o continue to permit the sale of tobacco products to adults[.]" TCA § 3(7), 123 Stat. at 1782. And, as above, it results in the imposition of a harsher regulatory scheme on Newly Deemed Products than on the Originally Regulated Products.

[29] *Cumulative Number of Product Applications Received Since Program Inception*, U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-total-product-submissions-since-Program-Inception (last updated Sept. 30, 2016).

V. THE FDA'S REJECTION OF "OPTION 2" EXEMPTING PREMIUM CIGARS IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW

At most, the FDA attempted to justify a painstaking product-by-product premarket review and testing process through anecdote. *See, e.g.*, 79 Fed. Reg. at 23,146–47. None of the agency's stories, however, ever implicated the *premium* cigar industry. Premium cigars are expensive (and thus practically inaccessible to minors) and are used by adults with far less frequency than other tobacco products.[30] They represent less than 0.1 percent of the U.S. tobacco market.[31] More importantly for purposes of the Final Rule, differentiation among premium cigars falls along lines having nothing to do with public health. There is no history in the premium cigar industry of manipulating nicotine levels or of additives making the products more attractive to minors. Rather, premium cigar varieties arise from aesthetic and taste preferences and natural agricultural variations that do not merit the arduous testing and crushing paperwork required for the agency to approve each separate product.

Agencies attacking a perceived regulatory problem are obligated to draw lines rationally. *See Bus. Roundtable*, 647 F.3d at 1154. The FDA knew this, so it proposed a regulation that would have more appropriately and effectively regulated the cigar industry by exempting premium cigars. *See* 79 Fed. Reg. at 23,151–52. The FDA proposed two options: "Option 1," which would subject all cigars to FDA regulation, and "Option 2," which would exempt premium cigars from the Rule. *Id.* The premium cigars exempted would be comprised solely of

[30] *See, e.g.*, AR130340–41; AR134768.

[31] AR130336; *see also* AR129595.

tobacco, would be made largely by hand, would lack characterizing flavors, and would be priced over a certain threshold, among other qualifications. *Id.* at 23,150.[32]

As a facially reasonable alternative, the FDA "had an obligation to consider" Option 2, a duty that entailed "respond[ing] to serious objections" and "adequate[ly]" explaining its decision. *Del. Dep't of Natural Res.*, 785 F.3d at 16–18; *see Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005). But the agency made no such effort to deal with the evidence in the record regarding its own proposal.

Instead, the FDA waved its hands at generalized public health concerns, claiming premium cigars were also unhealthy. *See* 81 Fed. Reg. at 29,020. It never once explained how running all types of premium cigars through the premarket review process, however, would advance the public health. Foremost in the agency's explanation should have been what the agency expected to find through premarket review of premium cigars, with some evidence that the anticipated conditions currently exist. The agency says nothing on the subject. *See id.* at 29,020–27.

The agency, in fact, seems to acknowledge that applying its full force to premium cigars is unnecessary. The FDA found that subjecting premium cigars to some, but not all, of the FDA's regulatory authority both would advance the public health and would dramatically reduce costs on small businesses. AR010647–48. In the Final Rule, however, the agency never runs to ground this alternative of its own creation.

Moreover, the agency seems to concede that it must make some finding that minors use premium cigars to include them in the Deeming Rule. *See* 81 Fed. Reg. at 29,020 (as basis for rejecting Option 2, "FDA has concluded that . . . premium cigars are used by youth and young

[32] The FDA's definition of "premium cigars" itself has problems but would have been a substantial improvement over the blanket rule issued by the agency. On remand, the agency would be required to reasonably address the nuances of its definition.

adults."). But the FDA's conclusion is not based on "substantial evidence." *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The FDA prominently announced that 3.8% of persons aged 12 to 17 who are "past 30 day cigar smokers" reported using an amorphously defined "premium" brand. *Id.* at 29,023 (citing AR020897-902 (Ref. 59)). What the agency leaves out is that 30-day cigar smokers are only approximately 3.3 percent of this age group, meaning that the agency was only referring to 0.001% of persons aged 12-17. *See* AR020898. Indeed, a recent FDA-funded study found that the frequent use of "traditional cigars," which would include premium cigars, by minors was so small that it could not be reliably measured. *See* Reynolds Decl. ¶ 26. In short, the agency risked the continued existence of a whole industry to benefit a statistically insignificant percentage of minors, without even explaining how the regulation will help reduce underaged use. In these circumstances, the D.C. Circuit has invalidated regulations under the APA. *See R.J. Reynolds.*, 696 F.3d at 1220 (a 0.088% projected reduction in cigarette use not "substantial evidence" supporting warning requirement).

Further, the FDA impermissibly failed to respond to important points and meaningful objections voiced in public comments. The FDA's responses to comments on Option 2 followed a common pattern: Commenters raised specific objections to Option 1's coverage of premium cigars, and the FDA responded in conclusory fashion that all cigar use causes health risks, thereby justifying the full panoply of TCA regulations. *See* 81 Fed. Reg. at 29,025–27. But that response omitted the entire consideration of the distinctly higher costs to premium cigar manufacturers resulting from imposing those regulations. In doing so, the FDA "entirely failed to consider an important aspect of the problem," namely the immense financial burdens of

regulation, the prospect of shuttering hundreds of small businesses, and the possibility of achieving the agency's public health goals through a less onerous alternative. *State Farm*, 463 U.S. at 43. This industry destruction is hardly justified when the agency cannot explain what it will detect in premarket review of premium cigars and how the regulation will address health risks.

If the agency still thought regulation of premium cigars were needed, it could have relied on Section 907 of the Act to devise appropriate tobacco product standards for premium cigars, without subjecting them to the full statutory premarket and testing scheme. *See* FD&C Act § 907(a)(3)(A), 21 U.S.C. § 387g(a)(3)(A) ("The Secretary may adopt tobacco product standards . . . if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health."). The FDA disclaimed this approach, asserting that Section 907's authority to create a tobacco product standard is unavailable unless the FDA first "deems" a product subject to the TCA. *See* 81 Fed. Reg. at 29,055. But Section 907 simply refers to "*tobacco product* standards," and does not reference the FDA's "deeming" authority. There is no reason why Section 907 does not draw from the general definition of "tobacco product" in the Act, which includes cigars. *See* FD&C Act § 201(rr)(1), 21 U.S.C. § 321(rr)(1).

The agency repeats the same mistake over and over again: It is all of the Act or none of the Act for premium cigars. That legal conclusion has no grounding in the Act, and is arbitrary and capricious. The proper remedy for the agency's failure adequately to consider alternatives for regulating premium cigars is remand to the agency to consider the full scope of its legal authority and adequately deal with the evidence and comments in the record. *See supra* at Section II.

VI. THE FDA'S DECISION TO IMPOSE USER FEES ON SOME BUT NOT ALL NEWLY DEEMED PRODUCTS IS CONTRARY TO LAW AND IN EXCESS OF STATUTORY AUTHORITY

To pay for the TCA's regulatory scheme, Congress imposed "user fees" on the "manufacturer[s] and importer[s] of tobacco products subject to" the TCA. FD&C Act § 919(a), 21 U.S.C. § 387s(a). Congress established an allocation formula that would assign user fees based on the classes of tobacco products in existence at the time of the TCA. *Id.* § 919(b)(2)(B)(i)–(ii), 21 U.S.C. § 387s(b)(2)(B)(i)–(ii). Nonetheless, Congress made clear that user fees *may* be imposed on tobacco products if they were either originally regulated by Congress or later deemed subject to the Act by the FDA. *Id.* § 919(b)(2)(B)(iii), 21 U.S.C. § 387s(b)(2)(B)(iii) ("[N]o user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) [originally regulated] or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter [newly deemed]."). All newly deemed products, including e-cigarettes, meet that simple standard.

The FDA, however, imposed user fees on all regulated tobacco products, except e-cigarettes. *See* 81 Fed. Reg. at 28,712. The FDA acknowledged that its decision created a "free rider" problem: Manufacturers and importers of e-cigarettes would not pay for their regulation; instead it would be charged to all other tobacco products, including cigars and pipe tobacco. *Id.* The FDA's only rejoinder is that it somehow lacked statutory discretion to impose user fees on e-cigarettes because they were not listed in Congress's initial allocation formula. *Id.* ("[T]he requirements of section 919 of the FD&C Act . . . prevent FDA from assessing user fees for deemed products other than cigars and pipe tobacco."). Even if it *could* create a new fee regime, the FDA said it would decline to do so because substantial work would be involved. *Id.* ("FDA would need to demarcate a new set of tobacco product classes among newly deemed tobacco products, and fashion an entirely novel framework for determining class percentage allocations

and allocations within each class of tobacco product."). In reaching the conclusion that it was all too hard, the FDA passed by common metrics that would subject new tobacco products to Congress's allocation formula (e.g., "20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars"). *Id.*

The FDA's selective implementation of a user fee is contrary to law for three reasons. First, by levying assessments against cigar and pipe tobacco, but not e-cigarette, manufacturers, the FDA turned what Congress designated as a "user fee" into a tax. Second, contrary to the FDA's claim, the Act explicitly grants authority to charge user fees for all products, including e-cigarettes. Finally, the FDA's User Fee Rule is bald economic favoritism raising constitutional problems under the equal protection component of the Fifth Amendment's Due Process Clause, which the Court should construe the statute to avoid.

A. Congress Deliberately Imposed a "User Fee," Not a Tax

Congress imposed "user fees," a phrase with a particular definition that is commonly understood. "User fees" are: (1) predicated on a voluntary act by a payer; (2) paid for a specific service or benefit, including the "benefit" of regulation; and (3) not meant for the benefit of others. *Nat'l Cable Television Ass'n v. United States*, 415 U.S. 336, 340–41 (1974); *see also* U.S. Gov't Accountability Office, GAO-08-386SP, *Federal User Fees: A Design Guide* 4–5 (2008). When a person or an entity is obligated to provide funds for government regulation of someone else, the payment is no longer a user fee but a tax. *See United States v. La Franca*, 282 U.S. 568, 572 (1931) (discussing difference between "tax" and "penalty"). With the TCA, the "bargain" of the user fee is straightforward: In exchange for the "benefit" of FDA regulation, manufacturers of tobacco products pay a user fee for the tobacco products they produce that funds the regulatory scheme. FD&C Act § 919(c)(2)(B)(i), 21 U.S.C. § 387s(c)(2)(B)(i) (user fees "are the only funds authorized" for agency's tobacco regulation activities).

The User Fee Rule, however, calls for *some* manufacturers of tobacco products to pay for the system as a whole, while others "free ride" by obtaining the "benefits" of regulation without any of the costs. Manufacturers that are required to pay user fees effectively subsidize the entry of "free riders" into the tobacco market. Because cigar, pipe tobacco, cigarette, and other manufacturers provide a benefit for "other members of society," e-cigarette manufacturers, the FDA's rule transforms Congress's user fee into a tax. *See Nat'l Cable Television Ass'n*, 415 U.S. at 341 (distinction between "fee" and "tax" depends on whether payer receives "benefit not shared by other members of society").

B. Congress Did Not Limit User Fees to the Tobacco Products Listed in its Allocation

Contrary to the agency's halfhearted suggestion, the text of the Act plainly does not restrict user fees to those tobacco products listed in the statutory allocation formula. The statute says that "the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of *tobacco products subject to this chapter*." FD&C Act § 919(a), 21 U.S.C. 387s(a) (emphasis added). It then sets out yearly total assessments, followed by allocations by product class, drawn from another statute. *Id.* § 919(b)(1)–(2), 21 U.S.C. § 387s(b)(1)–(2). That statute, the American Jobs Creation Act of 2004, lists product class allocations for fiscal years 2005 through 2014. 7 U.S.C. § 518d(b)–(c). Neither statute says that user fees shall be imposed *only* on those tobacco products identified in the allocation provisions. Yet "Congress generally knows how to use the word 'only' when drafting laws." *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d at 692, 697 (D.C. Cir. 2014).

Moreover, Section 919(b)(2)(B)(iii) states that user fees may be assessed so long as a tobacco product is "listed in section 901(b)" (*i.e.*, a product is originally regulated) or is "deemed by the Secretary in a regulation under section 901(b)" (*i.e.*, a product is newly deemed). FD&C

Act § 919(b)(2)(B)(iii), 21 U.S.C. § 387s(b)(2)(B)(iii). In other words, *all* deemed products, regardless of whether they are listed in Section 919(b)(2)(B)(i), are subject to user fees. Section 919(b)(2)(B)(iv) similarly shows Congress's intent that manufacturers and importers of regulated tobacco products pay their own way: If a product is not "deemed" but "otherwise would be assessed" user fees, the "amount of user fees . . . shall be reallocated to the classes of tobacco products [that are deemed and subject to user fees] . . . based on the same relative percentages otherwise determined under clause (ii)." *Id.* § 919(b)(2)(B)(iv), 21 U.S.C. § 387s(b)(2)(B)(iv). What the statute does *not* provide for is a shifting of user fees from deemed products not identified in the TCA to other tobacco products that happened to exist at the time of the TCA's enactment. The FDA's contrary interpretation flies in the face of these provisions.

The structure of the Act reinforces that user fees must be collected for all regulated entities. *Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1014 (D.C. Cir. 1999) (courts consider "the structure and context of the statutory scheme"). Taken to its logical end, FDA's interpretation of the user fee statute would yield absurd results that defy Congressional intent. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998) (absurd results from an agency interpretation that are "gravely inconsistent with the text and structure of the statute" invalidate a rule). Congress intended for the TCA to be self-sustaining, and to pay for regulation using "fees assessed on manufacturers and importers of *tobacco products*," not just the manufacturers of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. H.R. Rep. No. 111-58, pt. 1, at 21 (2009) (emphasis added). If e-cigarettes were not "tobacco products" as defined in the Act, the FDA would not have any authority to deem e-cigarettes subject to the Act. *See Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010) (the TCA "broadly defines tobacco products as extending to '*any* product made *or derived from tobacco*,'" including e-cigarettes).

Should e-cigarettes overtake large segments of the marketplace for tobacco products (a trend consistent with the current data), the FDA either would lack sufficient funding for its regulatory activities or saddle other tobacco products with the crushing expense of regulating e-cigarettes. Not only does the FDA's interpretation give rise to absurd results, but those results are "plainly at variance with the policy of the legislation as a whole"—for the TCA to be a self-sustaining regime. *See Nat'l Treas. Emps. Union v. Devine*, 733 F.2d 114, 120 (D.C. Cir. 1984) ("court[s] must look beyond the words to purpose of statute where its literal terms would lead to absurd results").

Should the Act be ambiguous, the agency's interpretation is plainly unreasonable. The FDA offered no reason why alternative methods of calculating user fees were too difficult to implement. *See* 81 Fed. Reg. at 28,712. While administrative convenience could potentially justify the reasonableness of FDA's construction of the user fee provisions, that rationale must be "reasonably explained." *Emily's List v. FEC*, 581 F.3d 1, 22 n.20 (D.C. Cir. 2009).

C. The User Fee Rule, As Impermissible Economic Favoritism, Raises Serious Constitutional Questions Under the Fifth Amendment

The FDA, without providing any meaningful reason, preferentially treats e-cigarettes by mandating that all other tobacco products fund their regulation. This is naked economic favoritism. While economic discrimination does not call for the most exacting form of judicial scrutiny, such discrimination still requires a rational basis under the Fifth Amendment's Due Process Clause. *St. Joseph Abbey v. Castille*, 712 F.3d 215, 223 (5th Cir. 2013) ("naked economic preferences," standing alone, are not a sufficient rational basis for economic discrimination). Administrative convenience—avoiding a few more paragraphs in the final rule—is hardly a rational basis. Although such a rationale could potentially satisfy rational basis review, it is contingent upon a showing that equal treatment would give rise to an administrative

inconvenience that would obviate whatever benefits that such treatment would yield. *See, e.g.*, *Armour v. City of Indianapolis*, 132 S. Ct. 2073, 2081 (2012) (holding that there was a sufficient rational basis because equal treatment would have yielded benefits "too small to justify the administrative expense"). The FDA made no attempt to clear that low bar, relying only on an incorrect understanding of the authorizing user fee statute.

To the extent there is any doubt about the Act's proper interpretation, the Court should resolve that doubt to require user fees to be distributed among all regulated tobacco products and to avoid an otherwise serious constitutional problem. *Nat'l Mining Ass'n v. Kempthorne*, 512 F.3d 702, 711 (D.C. Cir. 2008) ("[C]ourts make every effort to construe statutes so as to find their constitutional foundations and thus avoid needless constitutional confrontations.").

VII. THE FINAL RULE WAS BASED ON A FLAWED COST–BENEFIT ANALYSIS AND IMPOSES AN UNREASONABLE BURDEN ON SMALL BUSINESSES WITHOUT ADEQUATE EXPLANATION

A. The FDA's Cost–Benefit Analysis Was Fundamentally Flawed, Rendering its Rule Arbitrary and Capricious

The FDA found that the benefits of the deeming rule justified its staggering costs. 81 Fed. Reg. at 28,981. The agency was required to undertake a thorough cost–benefit analysis, but both its process and its conclusion were arbitrary and capricious.[33]

[33] Section 3(8) of the TCA declares that one of the purposes of the Act is "to impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(8), 123 Stat. at 1782 (emphasis added). The Supreme Court has made clear that this sort of value-laden language mandates consideration of all relevant factors, including the rule's costs and benefits. *See Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (a statutory directive to find regulations "appropriate and necessary" entails a cost–benefit analysis). Moreover, by endeavoring to perform a cost–benefit analysis, the FDA assumed the obligation to ensure that its calculations were accurate. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012) ("[W]hen an agency decides to rely on a cost–benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable."); *see also, e.g.*, 81 Fed. Reg. at 28,980–81 (describing the costs and benefits of the rule); *id.* at 29,074–76 (summarizing the FDA's analysis of impacts under Executive Order 12,866 and the Regulatory Flexibility Act, among other authorities); *id.* at

First, the FDA's analysis was premised on unquantifiable and speculative benefits. The agency admitted that it was unable to predict the rule's benefits: "The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time." 81 Fed. Reg. at 29,075. The Small Business Administration criticized this approach from the beginning, but the agency did nothing to marshal any additional data in the two years between its Preliminary Regulatory Impact Analysis and the Final Rule.[34] The agency's only effort was to lean on data regarding the benefits of regulating cigarettes and smokeless tobacco, notwithstanding their different user cohort and patterns, an exercise fraught with error as explained below.[35]

At the bottom of the FDA's reliance on unquantifiable benefits is its inability to show that and how the Rule will *cause* benefits to public health. There is a difference between an agency identifying a public health problem and showing it has a regulatory solution. It is little surprise, for example, that the agency could not demonstrate how much premarket review of

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29,075 ("For the reasons provided elsewhere in this preamble and in the analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs.")

[34] *See* AR082216–18; *see also* AR129925–26; AR130357–58; AR129611–12; AR159724. *Compare* AR010643 ("The lack of direct evidence and uncertainty associated with the indirect evidence prevented quantification of the benefits and some part of the costs of the proposed rule."), *with* AR023932 ("We note that we have not quantified the benefits of the proposed or final rule, and we are unable to quantify any possible unintended offsetting effects."), *and* AR023978 ("[W]e cannot quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects.").

[35] *See* AR023974–75 (predicting "[i]mproved effectiveness of sales restrictions" and "curb[ed] sales to youth," without considering the differing sales avenues for various tobacco products); AR023976 (predicting "fewer harmful or addictive products reaching the market" and "increase[d] product consistency" from premarket review, without distinguishing among tobacco products); AR023976 (predicting "reductions in use, switching to less risky products, and compensating health behaviors" from all combusted tobacco products, without differentiation).

cigars will benefit the public health, given the absence of evidence that variations in cigars and pipe tobacco, in and of themselves, are threatening the public health.

All the agency could do is point to the future. It says the deeming rule is different: It is an "enabling regulation" that will allow the "FDA to issue further regulations" that "will have their own costs and benefits." 81 Fed. Reg. 29,075. But the costs of the Rule are real and immediate, not contingent on future agency action. The FDA was fully capable of coupling the deeming rule with other attempted regulations of cigars and pipe tobacco, as the warning provisions of the rule so demonstrate. The agency cannot justify the costs of this Rule by what it *might* do through future rules. The result is nothing but hope and assertions of health benefits to offset the demonstrably devastating costs of the Rule on small businesses in the cigar and pipe tobacco industries.

These failings render the FDA's rulemaking arbitrary and capricious. An agency "may not shirk a statutory responsibility simply because it may be difficult." *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010). Regulatory bodies "by nature work under conditions of serious uncertainty, and regulation would be at an end if uncertainty alone were an excuse to ignore a congressional command." *Pub. Citizen v. FMCSA*, 374 F.3d 1209, 1221 (D.C. Cir. 2004). Consistent with these principles, courts have not hesitated to hold rules arbitrary and capricious where the issuing agency has failed to quantify important costs and/or benefits. *See Bus. Roundtable*, 647 F.3d at 1150–51 (agency "did nothing to estimate and quantify the costs it expected companies to incur" from its proxy-access rule, despite the "read[y] availabil[ity]" of empirical evidence on the subject, and "relied upon insufficient empirical data," which were "admittedly (and at best) 'mixed'"); *Chamber of Commerce*, 412 F.3d at 143–44 (agency arbitrarily declined to estimate costs of corporate-governance rule).

The FDA tried to distract from the absence of quantifiable benefits through the "breakeven" method. *See* 81 Fed. Reg. at 29,075. The "breakeven" method takes the *quantified* costs of a rule, and asks how much in otherwise *unquantified* benefits the rule would need to yield to "break even." AR023922. One problem with this analysis is that it compares apples to oranges, contrasting the costs the agency can prove, which are far smaller than the actual costs of the regulation, with the broader and amorphous benefits it cannot. *Id.* It then takes those quantified costs and divides them by the total number of users, to derive what each person would have to pay for the regulatory benefits. AR024026–27. Here, the agency conveniently concluded that its regulation costs only $2 a user and it must be worth at least that much. AR024027. The agency's conclusion is nothing more than assertion, and hardly a relevant one, but even its work along the way was arbitrary.

The FDA assumed that *all roughly 35 million current users of all newly deemed tobacco products*, adults and youth alike, would benefit *equally* from *all provisions* of the deeming rule; the agency conflated all users, regardless of patterns of usage, and all newly deemed tobacco products, with no regard for their vast diversity. A smaller denominator, or even the obvious recognition that all users of cigars, pipe tobacco, and e-cigarettes might not derive the same benefits from the rule, would dramatically change the calculation. Scholars have broadly criticized "breakeven analysis," and the FDA's version is a case in point.[36]

[36] *See, e.g.*, Daniel A. Farber, *Breaking Bad? The Uneasy Case for Regulatory Breakeven Analysis*, 102 Calif. L. Rev. 1469, 1479 (2011) ("although breakeven analysis may sometimes be a useful gauge, it also poses some significant risks," including the risk that "we will make off-the-cuff comparisons that seem intuitively appealing but that actually have no logical basis because they compare magnitudes along entirely different dimensions"); Richard L. Revesz, *Quantifying Regulatory Benefits*, 102 Calif. L. Rev. 1423, 1427 (2014) (breakeven analysis is "only a second-best alternative to the actual valuation of [a] nonquantifiable benefit").

Second, the FDA's analysis explicitly rested on incomplete and inaccurate data. Among the data the FDA said was missing: Data on "usage patterns and health risks for deemed products," AR023927; data on the number of retailers who blend pipe tobacco or the number of hand rollers of premium cigars who sell directly to retailers or consumers, AR023938; data on the number of cigar products in the market, AR023939, AR023984–86; data on the costs of HPHC testing, AR023945; data on cigar samples and associated costs and benefits, AR023953; data on "the impacts of warning labels, premarket review, and marketing restrictions" on cigars and pipe tobacco, AR023973; and data on the cost of premarket applications, AR023996, and substantial equivalence reports, AR024003–04. And this list is hardly exhaustive.[37]

The FDA attempted to fill the glaring gaps in its data through estimates and extrapolations from the agency's experience regulating cigarettes. *See* AR023934 (costs), AR023973 (benefits). However, the agency failed to account for the many material differences in products, user bases,

[37] *See, e.g.*, AR023929 (explaining that the "literature concerning the extent to which individuals are exposed to second-hand cigar and pipe tobacco smoke is limited"); *id.* ("We do 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."); *id.* (noting that "the substitutions that occur when many tobacco products' prices rise would be highly uncertain, with the public-health implications impossible to predict"); AR023932 ("Potential substitution towards black market or do-it-yourself products could affect the public health benefits of this final rule. We are unable to predict the likelihood or size of this effect."); AR023933 (discussing the "uncertainty about the effects of premarket authorization requirements on the magnitude of exit across market segments" and the agency's resulting difficulty "quantify[ing] with confidence the number of products that would be taken off the market"); AR023938 ("Without knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities."); AR023957 ("[W]hile we think the price increase will likely be small for traditional tobacco products, we are unable to estimate the effect of this regulation on prices."); AR023958 ("While we acknowledge that there likely will be product exit and a reduction in variety, we are unable to estimate the value of this loss in consumer choice."); *id.* ("We are unable to estimate the reduction in revenues that would be associated with a possible reduction in consumption."); AR023996 (remarking that PMTAs "may or may not require significant outlays on original research and testing, depending on the extent to which firms can compile the expected elements of the PMTA from existing information").

and usage patterns between cigars and cigarettes.[38] This reasoning lays bare the dearth of analysis behind the premarket review scheme, as cigars and pipe tobacco lack the history of product manipulation allegations in the cigarette industry. Casually hopping from industry to industry, the FDA relied on speculation, arbitrarily rejected contrary evidence, and failed to account for material differences among regulated entities. *See Bus. Roundtable*, 647 F.3d at 1150–51, 1154–56 (agency rested on "mere speculation" regarding director behavior, and failed to consider the distinctive features of investment companies, in projecting the costs and benefits of the proxy-access rule).

Third, many of the FDA's estimates were based on assumptions contradicting the evidence in the administrative record. For instance, the FDA predicted "relatively low" rates of market exit for cigars, pipes, and pipe tobacco "because many products will be grandfathered and most new products will be able to use generally lower-cost pathways to marketing authorization." AR023989; *see also* AR023994–95 (estimating a 60% grandfather rate for cigars, a 90% grandfather rate for pipes, and a 50% grandfather rate for pipe tobacco). Yet the overwhelming evidence confronting the agency suggested that the immense product variety, coupled with the 2007 predicate date, would close the grandfathering and substantial equivalence pathways for swaths of cigars and pipe tobacco.[39] Stunningly, the FDA *did not even estimate* the costs of premarket applications for cigars and pipe tobacco; it simply assumed that *not a single one of these products* would require such an application. AR024006–07; *see* AR023996–4003 (estimated premarket application costs for e-liquids and electronic nicotine delivery systems).

These empirical shortcomings further doom the rule. "[A]gencies do *not* have free rein to use inaccurate data." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56 (D.C. Cir. 2015). "If an agency fails to examine the relevant data—which examination could reveal, *inter alia*, that the

[38] *See supra* Section II.

[39] *See supra* Section II.

figures being used are erroneous—it has failed to comply with the APA." *Id.* at 57. Equally, an agency may not "duck serious evaluation" of potential costs identified in public comments. *Bus. Roundtable*, 647 F.3d at 1152.

B. The FDA's Rule Places an Unreasonable Burden on Small Businesses, Contrary to the APA and the Regulatory Flexibility Act

The FDA's final rule imposes staggering costs on small businesses without adequate justification by the agency. As the Regulatory Flexibility Act ("RFA") makes the interests of small businesses a "relevant factor" for qualifying rules, 5 U.S.C. §§ 603–604, "the APA together with the Regulatory Flexibility Act require that a rule's impact on small businesses be reasonable and reasonably explained," *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009).

The record is replete with evidence demonstrating that the costs of the rule fall disproportionately on small businesses. The agency acknowledged that 90 percent of the entities affected by the final rule were small businesses, AR024044; up to half of the handmade cigars currently available would cease to be marketed in the United States, AR023933; and the estimated costs to small cigar manufacturers or importers would be between $277,750 and $397,350 upfront and no less than $235,060 annually thereafter, AR024043. In a moment of remarkable candor, the FDA conceded that "the traditional segment of the cigar market . . . may be more affected to the extent that it is characterized by a large number of low volume products," that it was "unable to rule out the potential for [the smallest establishments] to be significantly affected by this rule," and that "some firms may exit the market." AR024042–43.

The FDA refused to give due consideration to regulatory alternatives projected to afford meaningful relief to small businesses. The FDA recognized that it could achieve its stated public health goals by subjecting premium cigars to only some of the regulatory regime, and that this

option would considerably reduce the burden on small businesses, but it rejected the option without any serious quantitative analysis. AR023968, AR024045.[40] An office within the Small Business Administration ridiculed the agency's treatment of less destructive alternatives.[41] Likewise, the FDA unreasonably declined to even consider changing the 2007 predicate date as a regulatory alternative, despite evidence that this approach would significantly alleviate the burden on small businesses.[42] And it only compounded this error by assuming, contrary to all available evidence, that 60% of cigars, 90% of pipes, and 50% of pipe tobacco products would be grandfathered using the 2007 predicate date, artificially reducing the incidence of the 220-hour outlays it estimated for *each* full substantial equivalence application. AR023947, AR023995, AR024003.

In short, the FDA failed to engage in the requisite "reasonable, good faith effort to canvass major options and weigh their probable effects." *Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 43 (D.D.C. 2000). As "[t]here is no discussion of what, if any, steps the agency took to minimize the significant economic impact on small business," or of "why those alternatives were rejected," the rule violates the APA and must be vacated. *Id.* at 44.

[40] In its general assessment of alternatives, the agency had projected cost savings of between $15.2 million and $42.6 million from Option 2. AR024033. The agency's only explanation for its decision not to perform a like quantitative analysis in its RFA assessment was that it "d[id] not know the number of manufacturers and importers of premium and non-premium cigars." AR024045.

[41] AR082217–18.

[42] *See, e.g.*, AR129901–04; AR159712.

VIII. THE FINAL RULE'S WARNING LABEL REQUIREMENTS VIOLATE THE FIRST AMENDMENT

For sixteen years, the majority of the cigar market has been required to display health warnings mandated by a settlement with the FTC. *See* 79 Fed. Reg. at 23,163.[43] Those not covered by the FTC consent decree post warnings required by the State of California on all of their U.S. packaging. AR021315. The FDA, without studying the efficacy of the existing warnings, made them bigger, expanded them to cover two principal product panels, and confiscated a *dramatically* larger amount of cigar packaging, crowding out manufacturers' ability to speak to their consumers. *See* Declaration of Rocky Patel ("Patel Decl.") ¶¶ 7, 9-11 & Exs. A and B; Declaration of Janelle Rosenfeld ("Rosenfeld Decl.") ¶¶ 3-5 & Ex. A.

Under the FDA's new rule, packages and advertisements for cigars must display one of six warnings randomly over a 12-month period in accordance with a "warning plan" submitted to and approved by the FDA. 81 Fed. Reg. 29,061. As to content, the FDA rule adds one statement to the FTC consent decree rotation. *Id.* at 28,979. The big differences are in size and placement. On labels and packages, the warnings must occupy *30 percent* of the *two* principal display panels and must be in at least 12-point font. *Id.* at 29,061. The "principal display panels" are those "most likely to be displayed, presented, shown, or examined by the consumer." *Id.* at 29,104. For advertisements, the required warning statements must be rotated quarterly, in alternating sequence, and must cover at least 20 percent of print advertisements and other advertisements

[43] On June 26, 2000, seven leading cigar firms, comprised of about 95% of the U.S. cigar market, agreed to display a series of five warning statements "clearly and conspicuously" on their advertising and packaging in settlement agreements with the FTC. *See* Press Release, Fed. Trade Comm'n, FTC Announces Settlements Requiring Disclosure of Cigar Health Risks (June 26, 2000), *available at* https://www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosure-cigar-health-risks (hereinafter "FTC consent decree"). The FTC consent decree set out specific requirements for the location and size of the warnings depending on the size and shape of the package. *See* FTC Decision and Order, *In the Matter of Consolidated Cigar Corporation*, Docket No. C-3966 (Aug. 18, 2000).

with a visual component. *Id.* at 29,061. For cigars sold individually and not in product packages, retailers are required to post signs within three inches of the point-of-sale register listing the six warnings on a sign no smaller than 8.5" x 11". *Id.* These new warnings for packages and advertisements are 300-400% larger than those required by the FTC consent decree, and cover two display panels, rather than one. *See* Patel Decl. ¶¶ 6-7 & Exs. A and B; Rosenfeld Decl. ¶¶ 3-5 & Ex. A. Compared to the California labels, the FDA's labels are approximately ten times larger. *Id.* ¶ 5.

The FDA also imposed new warning label requirements on pipe tobacco. 81 Fed. Reg. at 29,060. Under the labeling rule, all pipe tobacco packages must bear the following warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." *Id.* at 29,104. The warning must occupy at least 30 percent of the two principal display panels and must be printed in at least 12-point font. *Id.* For print advertisements and other advertisements with a visual component (e.g., signs, shelf-talkers, websites, and e-mails), the warning must occupy at least 20 percent of the area of the advertisement and must be printed in at least 12-point font. *Id.* at 29,104–05.

These new warning label requirements violate the First Amendment. A hallmark of cigar and pipe tobacco marketing, particularly in the premium cigar industry, is aesthetically pleasing packaging connoting luxury and distinctiveness.[44] They also communicate information about the products, such as country of origin, seed varietal, and the process of manufacture. The symbols, trademarks, and trade dress of the package send a message to consumers about the qualities of

[44] *See* AR130350 ("Premium cigars routinely come packaged in ornate boxes, which are part and parcel of the consumer buying experience, and an integral part of cigar manufacturers' marketing."); AR134770 ("Premium cigars are usually packed in decorative boxes, which our customers have come to appreciate as part of the buying experience. As retailers, our humidors are filled with those ornate boxes."); Declaration of John Anderson ("Anderson Decl.") ¶ 9.

the product and the craftsmanship with which it was assembled. *See generally Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985) ("The use of illustrations or pictures in advertisements serves important communicative functions: [I]t attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly."). Commercial packaging is a medium of commercial speech and is entitled to First Amendment protection. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 480-83 (1995) (First Amendment applies to information conveyed on beer labels); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 567 (1980) ("[T]he suppression of advertising reduces the information available for consumer decisions and thereby defeats the purpose of the First Amendment."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762, 765 (1976) (speech "which does 'no more than propose a commercial transaction'" is protected by the First Amendment); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 96–97 (2d Cir. 1998) (beer label that "communicates no information beyond the source of the product" is entitled to protection as commercial speech).

The FDA's required warning labels will commandeer a significant amount of space on cigar and pipe tobacco packaging and advertisements and effectively crowd out manufacturers' own communication with consumers. As such, the Rule must pass the standard for commercial speech restrictions under *Central Hudson* and the standard for compelled commercial warnings under *Zauderer*.[45] The warning label regulation fails both tests.

[45] The D.C. Circuit has cautioned that compelled disclosure may violate the First Amendment as a prohibition on speech but has declined precisely to specify "when the compulsion to speak becomes more like a speech restriction than a disclosure." *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 507 & n.3 (D.C. Cir. 2016).

A. The FDA Has Failed to Justify its Restriction of Cigar and Pipe Tobacco Manufacturers' Commercial Speech

The FDA has the burden of justifying a regulation restricting the space and prominence of a company's communication with consumers. *See Edenfield v. Fane*, 507 U.S. 761, 770 (1993). The FDA must prove that: (1) the asserted governmental interest is substantial; (2) the regulation directly advances the governmental interest asserted; and (3) the regulation is not more extensive than is necessary to serve that interest. *Cent. Hudson*, 447 U.S. at 566. It cannot do so.

1. The FDA's cigar and pipe tobacco warning label requirements do not serve a substantial government interest

The FDA's stated interest in the new warning label requirements is "to help current and potential tobacco users understand and appreciate the serious adverse health consequences associated with tobacco use and the addictive nature of tobacco products." 79 Fed. Reg. 23,163; *see also id.* at 23,165, 23,166; 81 Fed. Reg. at 28,981; AR023975. Standing alone, this is not a substantial interest under *Central Hudson*.

In *R.J. Reynolds Tobacco Co. v. FDA*, the FDA attempted to justify a cigarette warning label because it was "'effectively communicating health information' regarding the negative effects of cigarettes." 696 F.3d at 1221.[46] The D.C. Circuit found that an interest in "'effective' communication is too vague to stand on its own," as it is "merely a description of the means by which it plans to accomplish its goal of reducing smoking rates, and not an independent interest capable of sustaining the Rule." *Id.* Likewise, efforts to reduce *adult* use of a legal product, such as cigarettes or cigars, cannot justify restrictions of speech:

[46] *American Meat Institute* overruled *R.J. Reynolds*, a compelled speech case, to the extent that it "may be read as . . . limiting *Zauderer* to cases in which the government points to an interest in correcting deception." *Am. Meat Inst.*, 760 F.3d at 22–23. But *R.J. Reynolds*' analysis of *Central Hudson* still stands.

> The State's interest in preventing underage tobacco use is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products. . . . As the State protects children from tobacco advertisements, tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication.

Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 564 (2001) (citations omitted). The Supreme Court has recognized only one legitimate interest justifying restrictions of commercial speech regarding tobacco products: Reducing underaged initiation and use. *Id.* at 555.

Underaged use, however, simply is not the same issue for cigars, particularly premium cigars, as it is for cigarettes. *See* Reynolds Decl. ¶¶ 25-48. Only a small percentage (2.5%) of the underaged reported using cigar products, and dramatically fewer for premium cigars, and the number of the underaged using cigars and pipe tobacco has decreased over time. *Id.* ¶¶ 25-27, 29, 39, 44-46. Indeed, a recent FDA-funded study reported *no statistically significant use* of premium cigars by the underaged. *Id.* ¶¶ 25-26. The agency made *no* specific findings regarding underaged pipe tobacco use in the Final Rule and ignored a study reporting youth usage rates of 0.2% for pipe tobacco. 81 Fed. Reg. at 29,048–49. Nor have there been congressional findings that cigar or pipe tobacco manufacturers are targeting their marketing or advertising at the underaged or manipulating their products to appeal to the underaged. *Compare* TCA § 2(47)–(49), 123 Stat. at 1781 (findings regarding marketing and product manipulation in *cigarette* industry). The evidence in the record simply does not indicate a regulatory problem with respect to underaged use of cigars or pipe tobacco, much less one that the warning labels would begin to solve.

2. The warning labels do not directly or materially advance the reduction of underaged cigar and pipe tobacco initiation and use

The FDA also has failed to show that the new warning labels will actually reduce underaged cigar and pipe tobacco initiation and use. The FDA's burden "'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Rubin*, 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 770–71). The agency has conceded, however, that "[r]eliable evidence on the impacts of warning labels . . . on users of cigars [and] pipe tobacco . . . does not, to [the agency's] knowledge, exist," AR023973, and claims it needs to study the issue, *see, e.g.*, 81 Fed. Reg. at 29,065. This is a problem: "*Central Hudson* requires FDA to find and present data supporting its claims *prior to* imposing a burden on commercial speech." *R.J. Reynolds*, 696 F.3d at 1221.

Evidence regarding the efficacy of larger warning labels in reducing *cigarette* use is not enough to justify the agency's broad speech restrictions on cigars and pipe tobacco, which have dramatically different usage patterns, especially among the underaged. Even if such evidence were relevant, it shows that warning labels do not materially affect the causes of underaged smoking. *See* Reynolds Decl. ¶¶ 71-80. The causes of underaged smoking concern peer pressure, modeling, and underaged access and availability. *See id.* ¶¶ 54-70. The record does not include, and Plaintiffs' expert has not found, evidence that underawareness of the health risks of smoking is a cause for underaged use. The agency—just like in *R.J. Reynolds*—did not present data showing that better communication of health risks will reduce smoking among the underaged, a population that regrettably feels invincible no matter what they are told. *See id.* ¶ 59.

3. The warning label requirements are not narrowly tailored

The FDA fails both aspects of the "narrowly-tailored" requirement. First, narrow tailoring "requires a reasonable fit between the means and ends of the regulatory scheme." *Lorillard Tobacco*, 533 U.S. at 561 (discussing *Cent. Hudson*, 447 U.S. at 569). Second, the FDA must show that there are no other options available that "could advance [its] asserted interest in a manner less intrusive to [Plaintiffs'] First Amendment rights." *Rubin*, 514 U.S. at 491.

The FDA hardly has shown a "reasonable fit" between its required warning labels and its stated goals. The warnings commandeer a significant portion of a product's packaging and advertising, occupying 30% of the product's two principal displays and 20% of any advertising. *See Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (finding that a four-square-inch warning label required to be placed on a 7.5 by 5.5 inch DVD box "*literally* fails to be narrowly tailored—the sticker covers a substantial portion of the box"). The agency has failed to demonstrate why the FTC consent decree or California label requirements for cigars are not adequate or, most importantly, why larger warnings would be more effective. *See* 81 Fed. Reg. at 29,066.[47]

And, of course, the FTC consent decree and California labels on cigars are alternatives less restrictive of speech than the FDA's larger warnings. But the FDA marshalled no data

[47] The FDA may argue, as it did in its Final Rule, that the decision in *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), supports the size of the warning labels. *See* 81 Fed. Reg. at 28,988. In *Discount Tobacco*, however, the court addressed only the standard for compelled commercial disclosures under *Zauderer*. *See* 674 F.3d at 558. Intermediate scrutiny under *Central Hudson* is required here, given the restrictive impact of the warning labels on cigar packaging. *See supra* at Section VIII(A)(1). The *Discount Tobacco* court also reviewed the warning label requirements in that case in the context of decades of alleged conspiracy by certain cigarette companies to deceive the public about the risks and addictiveness of cigarette smoking and their own product manipulation. *See* 674 F.3d at 562–63. There have been no similar findings in the case of cigar manufacturers.

demonstrating the FTC warnings were failing to inform consumers about the health risks of smoking, despite having *sixteen years* to study their effect. The FTC warnings are only one of many alternatives less restrictive of speech that the agency failed to analyze. The government "could disseminate its anti-smoking message itself" through government advertising and public information campaigns. *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266, 276 (D.D.C. 2012), *aff'd on other grounds*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst.*, 760 F.3d 18. There are numerous other established methods that are more likely than larger health warnings to reduce underage tobacco use, including: Raising the minimum legal age to purchase tobacco products; increasing penalties and enforcement measures relating to selling, possessing, or using tobacco products by the underaged; increasing support for programs aimed at the social factors underlying tobacco use by the underaged; and raising the prices of tobacco products. *See* Reynolds Decl. ¶¶ 81-83. All of these measures are directed at the root causes of underaged tobacco use, and involve no restrictions of speech. After all, "regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

Nor has the FDA shown that it "'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999); *see also Lorillard*, 533 U.S. at 564–65. Many manufacturers rely on their ornate packaging as a significant way to differentiate their products at the point-of-sale. *See* Patel Decl. ¶ 4; Anderson Decl. ¶ 9. This is particularly important in the premium cigar industry, where customers are often not brand-loyal and regularly look for new products, such that packaging is a means of brand competition.[48] The warnings nearly destroy

[48] *See* AR129897.

this medium, *see* Patel Decl. ¶ 11, but to no end as the agency admits there is no reliable evidence on the impact of warning labels on users of cigars or pipe tobacco, AR023973. The FDA failed to consider the differences from cigarettes in its regulatory scheme. *See Lorillard*, 533 U.S. at 565 ("[T]o the extent that cigar products and cigar advertising differ from that of other tobacco products, that difference should inform the inquiry into what speech restrictions are necessary.").

B. The FDA's Warning Label Requirements Also Fail the Standard for Compelled Commercial Warnings

The Rule also fails the First Amendment standards for compelled commercial disclosures set forth by the Supreme Court in *Zauderer*.

First, there has been no charge of consumer "deception" by cigar or pipe tobacco manufacturers, which is the historical foundation for *Zauderer*'s relaxed scrutiny. *See* 471 U.S. at 651.

Second, the new and unduly burdensome warning labels are "unjustified." In *American Meat Institute*, the D.C. Circuit questioned, but did not resolve, "whether *Zauderer* would permit government reliance on interests that do not qualify as substantial under *Central Hudson*'s standard, a standard that itself seems elusive." 760 F.3d at 23. As discussed above, the agency's stated interest in increasing understanding of the health risks of cigar and pipe tobacco products is not itself an independent value, and the agency has shown no data demonstrating that large (or larger) labels will reduce the incidence of smoking. *See supra* at pp. 51-55.

Third, in the absence of demonstration of need, the size of FDA's warning labels is "unduly burdensome." *See Am. Meat Inst.*, 760 F.3d at 26 (citing *Zauderer*, 471 U.S. at 651). The warning labels confiscate a significant amount of space on cigar and pipe tobacco manufacturers' product packages, where manufacturers would otherwise communicate the

qualities of their products through distinctive trade dress. This is quintessential undue burden. *See, e.g.*, *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994) (disclosure requirement which effectively prevented certain advertisements was unduly burdensome); *Dwyer v. Cappell*, 762 F.3d 275, 284 (3d Cir. 2014) (attorney advertisement rule requiring publication of complete court opinions rather than excerpts commenting on attorney's abilities "is so cumbersome that it effectively nullifies the advertisement"). The warning label requirements therefore fail to satisfy First Amendment scrutiny under either a *Zauderer* or *Central Hudson* analysis.

IX. THE AGENCY UNREASONABLY IMPOSED NEW WARNING LABEL REQUIREMENTS WITHOUT MAKING THE STATUTORILY-MANDATED FINDINGS

The Court, however, need not reach the constitutional question. That is because the FDA's warning label mandate also violates the Act.

The FDA has imposed the new warning labels requirements without even attempting to make the findings Congress required before mandating warning labels. Section 906(d) of the Act authorizes the FDA to require health warnings, "if the Secretary determines that such regulation would be appropriate for the protection of the public health." FD&C Act § 906(d)(1)–(2), 21 U.S.C. § 387f(d)(1)–(2). The Secretary is required to make specific findings in this regard:

> The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits of the population as a whole, including users and nonusers of the tobacco product, and taking into account—
>
> > (A) *the increased or decreased likelihood that existing users of tobacco products will stop using such products*; *and*
> >
> > (B) *the increased or decreased likelihood that those who do not use tobacco products will start using such products.*

Id. § 906(d)(1), 21 U.S.C. § 387f(d)(1) (emphases added).

The agency, however, made no determination about the warnings' effect on decreasing cigar or pipe tobacco use or increasing cessation of such use. Instead, the agency simply asserted that the warning labels would help consumers "appreciate the risks" of cigars and pipe tobacco. *E.g.*, 81 Fed. Reg. at 29,064, 29,065, 29,070, 29,075. But that is not the inquiry Congress required. It required a finding that warnings would actually reduce cigar and pipe tobacco use. Stunningly, the FDA admitted it could not make the statutorily mandated finding: "***Reliable evidence on the impacts of warning labels . . . on users of cigars . . . [and] pipe tobacco . . . does not, to our knowledge, exist***." AR023973 (emphasis added). It said it would have to study the issue in the future. *See* 81 Fed. Reg. at 29,065 (the agency intends to "conduct research and keep abreast of scientific developments regarding the efficacy of the health warnings in the final rule and the ways in which their efficacy could be improved"). The statute requires findings on the "increased or decreased likelihood" of smoking initiation or cessation before warnings are imposed, not after. FD&C Act § 906(d)(1), 21 U.S.C. § 387f(d)(1).

Congress was wise to require explicit agency findings that a warning requirement would reduce tobacco use. That is because the *Constitution* requires the same evidence before the government restricts speech. *See supra* at pp. 52-53. If there were any ambiguity about the statutorily required findings before imposing a warning mandate, the Court should demand that the agency find specifically and with evidence that the warnings would reduce tobacco use to avoid the serious constitutional problems that would otherwise result.[49] *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

[49] This would not solve the constitutional problem altogether, given that reducing tobacco use *by adults* is not a substantial government interest, but it would certainly narrow the scope of the agency's constitutional error. *See supra* at pp. 51-52.

In any event, the statutory mandate to specifically reach whether and how the warnings mandate would reduce tobacco use demonstrates that the Rule is arbitrary and capricious in violation of the APA. "When Congress says a factor is mandatory, that expresses its judgment that such a factor is important. In accordance with this principle, we have held that 'the complete absen[c]e of any discussion' of a statutorily mandated factor 'leaves us with no alternative but to conclude that [the agency] failed to take account of this statutory limit on [its] authority,' making the agency's reasoning arbitrary and capricious." *Pub. Citizen*, 374 F.3d at 1216; *see State Farm*, 463 U.S. at 42–43. The agency conceded that it did not and could not reach an issue Congress made important. The rule is by definition arbitrary and capricious.

Further, the agency did not attempt to show why a change from the FTC consent decree or California schemes was needed for cigars, much less so much to justify the massive costs of the change. Each product will undergo a "major" labeling change, the labeling requirements are "a large contributor to the costs of this rule," and the costs are astronomical. AR023952, AR024017, AR024019. For example, one premium cigar manufacturer has 1,670 unique products.[50] Under the FDA's calculation of the cost for a warning change per product, this manufacturer will need to spend between $2,571,800 and $27,820,530. *See* AR024019.

In the face of these costs, the FDA summarily stated that it "has concluded that the formatting requirements for the health warnings, which are similar to the requirements for smokeless products and similar to those suggested by [WHO Framework Convention on Tobacco Control], are appropriate for the protection of the public health." 81 Fed. Reg. at 29,066. This does not explain why the existing requirements of the FTC consent decree are not also "appropriate for the protection of public health" or what the new warnings add that justifies

[50] AR130285–86 ; AR130361.

their massive costs. There is no question that making the FTC warnings mandatory for that segment of the market not covered by the consent decree would have been dramatically less costly.[51] It was arbitrary and capricious for the agency to upset the status quo without articulating a satisfactory explanation for its decision or considering reasonable alternatives. *See State Farm*, 463 U.S. at 43; *Del. Dep't of Natural Res.*, 785 F.3d at 16–18.

X. THE FDA ERRONEOUSLY INTERPRETED THE TCA TO TREAT RETAILERS WHO BLEND FINISHED PIPE TOBACCO AS TOBACCO PRODUCT MANUFACTURERS

The agency also erred in rewriting the statute to treat small-business pipe tobacco retailers as manufacturers when they blend two finished pipe tobacco products for their customers. In the preamble to the Final Rule, the FDA provided:

> All entities that meet the definition of "tobacco product manufacturer" in section 900(20) of the FD&C Act, ***including retail establishments that blend pipe tobacco***, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers.

81 Fed. Reg. at 29,049 (emphasis added).[52] The agency's interpretation has consequences rippling throughout the Final Rule, including by potentially roping retailers who blend pipe tobacco into its reference to "domestic tobacco manufacturing establishments" and the burdensome requirements of Section 905 of the Act to register with the agency, among many

[51] The agency's failure to seriously analyze the efficacy of larger warnings dovetails with the agency's disregard for the study and research Congress required from the Tobacco Products Scientific Advisory Committee (the "TPSAC" or the "Committee"). FD&C Act § 917(c), 21 U.S.C. § 387q(c). Citing First Amendment concerns, at least one commenter suggested that the FDA defer imposing the warning label requirements on Newly Deemed Products until the FDA or the TPSAC could complete scientific research on dependence issues, taking into account the distinctive usage patterns among different tobacco products. AR160638–39. The FDA declined and made no effort to avail itself of the TPSAC's institutional resources and expertise before subjecting cigars and pipe tobacco to an onerous new labeling regime.

[52] "Tobacco product manufacturer" is defined under the statute as "any person, including any repacker or relabeler, who—(A) manufacturers, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." FD&C Act § 900(20), 21 U.S.C. § 387(20).

other things. *See* 81 Fed. Reg. at 29,004, 29,049. The consequences of being classified as a tobacco product manufacturer are dramatic: Such retailers will be dragged through the extraordinarily expensive premarket review, product testing, ingredient listing, annual registration, and recordkeeping requirements described above. *See* FD&C Act §§ 904, 905, 909, 910, 21 U.S.C. §§387d, 387e, 387i, 387j. The result will be that retailers cease all blending of pipe tobacco, despite their customers' requests for it.

The agency's interpretation is wrong. Retailers blending finished pipe tobacco are not "manufacturers." They are simply taking two end-use, FDA-approved products and performing a service that consumers themselves could do on their own.[53] Congress understood this. When it referred to "manufacture" of tobacco products in Section 905 of the FD&C Act, it expressly distinguished retailers: "The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to *the person who makes final delivery or sale to the ultimate consumer or user*." *Id.* § 905(a)(1), 21 U.S.C. § 387e(a)(1) (emphasis added). Thus, a retailer—"the person who makes final delivery or sale to the ultimate consumer or user"—cannot be the same as a manufacturer under the Act.

Even if the statute were ambiguous on this point, the agency's interpretation is not reasonable. Instead, the FDA's position threatens to eliminate long-standing and well-known aspects of the industry without any clear statement of justification. Bulk tobacco that is "blended" is itself a finished tobacco product produced by a regulated tobacco product

[53] *See* AR130239–40 ("As a practical matter, FDA should not want to regulate mixing of blends by retailers because retailers receive products that were manufactured by persons subject to FDA's laws and regulations, and blend already mixed and/or processed products on a relatively small scale in a somewhat imprecise way."); AR081246–47 (same); Anderson Decl. ¶¶ 6-7.

manufacturer who will be subject to premarket review. The FDA has not suggested (nor could it) that blending of finished pipe tobacco chemically or physically alters the tobacco in any way, may cause a dangerous chemical reaction in combination, or presents any public health risk distinct from the end consumer products already approved by the FDA.[54] Presumably, the hundreds of years' experience in blending pipe tobacco would have alerted someone to an acute health risk by this point. In marked contrast, the agency specifically explained that the manifold chemicals in cutting-edge e-cigarette liquids could react in ways unforeseen by anyone other than experts. *See* 81 Fed. Reg. at 29,044–46.

The absence of any similar explanation for pipe tobacco is a hallmark of arbitrary and capricious overregulation. The APA expects and demands that agencies distinguish between industries: If there is evidence of public health problems for blended vaping, but not for pipe tobacco, the agency must treat those industries differently. *See Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 722-23 (D.C. Cir. 1988) (affirming remand of rule where secretary "too swiftly equated surface mining with underground mining for the purpose at hand," despite "'basic differences' between the two operations").

The FDA's interpretation also is unreasonable because it imposes a significant burden and expense on numerous small businesses around the country.[55] The agency admitted that it was "unable to estimate the number of retailers who blend pipe tobacco" and that, "[w]ithout

[54] *See* AR130204 ("To require both the manufacturer and a tobacco retailer to register, list pipe tobaccos and file product ingredient lists would be redundant, especially because pipe tobaccos that are blended together retain their characteristics after the blending, except a new overall flavor is created through the blend.").

[55] *See* AR130240–41 (requesting that FDA include fiscal impact of rule that would regulate retailers who blend tobacco and "include the impact on small, often family-owned, retail stores that blend pipe tobacco"); AR081247 (requirements are "burdensome for a small business owner and superfluous given that the products blended at my shop will have already been approved by the FDA").

knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities." AR023938; *see also* AR023917. The agency unreasonably punted on this issue. *See Bus. Roundtable*, 647 F.3d at 1148-49; *Chamber of Commerce*, 412 F.3d at 144 ("[U]ncertainty may limit what the Commission can do, but it does not excuse the Commission from its statutory obligation to do what it can to apprise itself—and hence the public and Congress—of the economic consequences of a proposed regulation before it decides whether to adopt the measure."); *supra* at Section VII(B).

XI. THERE IS NO BASIS IN THE STATUTE OR ADMINISTRATIVE RECORD TO TREAT PIPES AS "COMPONENTS" OF A TOBACCO PRODUCT

The FDA concluded that pipes are "components" of a tobacco product and therefore subject to the TCA. *See* 81 Fed. Reg. at 29,042. Its interpretation of the statute would require every pipe manufacturer, from one-man shops in the garage to large corporations, to undergo the crushingly expensive registration and premarket review process. The agency's contention is without merit.

The term "component" in the definition of "tobacco product" in § 201(rr) of the FD&C Act does not include pipes. "Tobacco product" is defined as "any product *made or derived from tobacco* that is intended for human consumption, including any component, part or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." FD&C Act § 201(rr)(1), 21 U.S.C. § 321(rr)(1). A "component" is a "*constituent part*" or an "*ingredient*." *See Component*, Merriam-Webster, http://www.merriam-webster.com/dictionary/component; New Webster's Comprehensive Dictionary of the English Language 207 (1985 ed.) ("component" means

"constituent").[56] A pipe is not a *constituent part* or *ingredient* of a product *made or derived from tobacco*, and therefore is not subject to regulation as a tobacco product under the Act.

This is borne out by the use of the term "component" in other parts of the statute. Elsewhere in the statute, the term "component" is used as a concept similar to terms such as "additive," "ingredient," and "constituent." *See, e.g.*, FD&C Act §§ 907(a)(3)(B)(ii) (discussing "an additive, constituent (including a smoke constituent) or other component of a tobacco product"), 907(a)(4)(B)(i) (discussing "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product"), 910(b)(1)(B) (requiring "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product"), 21 U.S.C. §§ 387g(a)(3)(B)(ii), 387g(a)(4)(B)(i), 387j(b)(1)(B); *see also* TCA § 3(5), 123 Stat. at 1782 (designating as one purpose of the Act "to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, *and other harmful components of tobacco products*" (emphasis added)). A statutory term is known by the traits of its companions, including other terms in a series. *See Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 575 (1995) (applying canon of *noscitur a sociis*). All of these terms denote a material that is integrated with a product made of tobacco. A pipe carries tobacco, it is not a part of it, and thus is not a "component" of a tobacco product.

Even if the term "component" were ambiguous, the agency's interpretation is not reasonable, particularly as applied to pipes. The FDA defined "component or part" to mean:

> any software or assembly of materials intended or reasonably expected: (1) [t]o alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) [t]o be used with or for the human consumption of a tobacco

[56] "In interpreting statutory texts courts use the ordinary meaning of terms unless context requires a different result." *Gonzales v. Carhart*, 550 U.S. 124, 152 (2007).

> product. Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102. The agency separately defined "accessories" because "accessories, unlike components or parts, are expected to have little direct impact on the public health." *Id.* at 28,975. There is nothing in the record to suggest that pipe architecture is being manipulated to make tobacco more addictive or dangerous and have any other direct effect on public health. *See id.* at 29,042.[57] Instead, differentiation among pipes is almost all for aesthetic reasons. *See* Anderson Decl. ¶¶10-11. Pipes are better classified as "accessories."

The FDA's interpretation will lead to regulatory burdens that pose an existential threat to the small craftsmen carving premium pipes. The FDA has not adequately considered the effect of this regulatory action on these particular small businesses. *See, e.g.*, AR023986 (estimating there are at least 4,610 different types of pipes, excluding hand-crafted pipes); AR023989 ("assum[ing]" that 5 percent of baseline newly deemed products, including pipes, will exit the market rather than submit a marketing application); AR024042–44 (failing to specifically address premium pipe craftsman in analysis of economic effect of rule on small entities); *see also supra* at Section VII(B). Thus, once again, the agency acted arbitrarily and capriciously in its failure to adequately assess the economic effects of its rule. *See Bus. Roundtable*, 647 F.3d at 1148–49.

CONCLUSION

Plaintiffs' motion for summary judgment should be granted.

[57] *See also, e.g.*, AR130248 ("PTC believes that there is no public health basis for regulating smoking pipes because pipes have no more of an impact on the public health than humidors or lighters that are exempt from regulation. Subjecting pipes to regulation would overwhelmingly increase the burden on FDA and on pipe manufacturers with no concomitant benefit to the public health.").

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