UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 1:16-cv-01460 (APM)**
	)	
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

On May 10, 2016, the U.S. Food and Drug Administration ("FDA") published a final rule "deeming" cigars, pipe tobacco, and certain other products (e.g., e-cigarettes) subject to the federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301, *et seq.*, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"). Known as the "Deeming Rule," the FDA's action subjects these newly "deemed" products to comparable statutory and regulatory requirements already imposed on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. At the same time, the FDA promulgated a separate rule, referred to as the "User Fee Rule," which assesses "user fees" on manufacturers and importers of cigars and pipe tobacco, but not other newly deemed products, like e-cigarettes. The FDA is statutorily authorized to collect user fees for the purpose of funding the FDA's regulation of tobacco products under the FD&C Act and the TCA.[1]

[1] Hereinafter, for ease of reference, the court refers to the FD&C Act, as amended by the TCA, as the "TCA."

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Plaintiffs in this case are three non-profit associations that represent cigar manufacturers, importers, distributors, suppliers, and consumers, as well as premium cigar and tobacco retail shops. They brought this action in July 2016 against the FDA and its Commissioner, and the U.S. Department of Health and Human Services ("HHS") and its Secretary (collectively, "Defendants"), challenging the Deeming Rule and the User Fee Rule on a host of grounds.[2] For reasons explained later in this opinion, not all of Plaintiffs' challenges to the Rules are presently before the court. Instead, the court addresses only the following subset of challenges: (1) the imposition of health warning requirements for cigar packaging and advertisements; (2) the assessment of user fees on cigar and pipe tobacco products, but not on another newly deemed product, e-cigarettes; (3) the treatment of retailers who blend pipe tobacco in-store as "manufacturers" subject to the regulatory requirements of 21 U.S.C. § 387e; and (4) the classification of pipes as "components" of tobacco products, thereby subjecting pipe makers to regulation. Plaintiffs also have moved to preliminarily enjoin implementation and enforcement of the Deeming Rule's health warning requirements.

For the reasons set forth below, the court grants in part and denies in part the parties' cross-motions for partial summary judgment and denies Plaintiffs' motion for a preliminary injunction as moot. The Deeming Rule's health warning requirements are upheld in all respects, as is the User Fee Rule in its entirety. The court also affirms the agency's classification of pipes as "components or parts" of tobacco products under the TCA. The court, however, concludes that Defendants' rationale for subjecting retailers who blend pipe tobacco in-store to the requirements of 21 U.S.C. § 387e is arbitrary and capricious and therefore remands that issue to the FDA for further consideration.

[2] Pursuant to Federal Rule of Civil Procedure 25(d), Alex M. Azar II, Secretary of Health and Human Services, and Dr. Scott Gottlieb, Commissioner of Food and Drugs, are substituted for their predecessors in office.

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II. BACKGROUND

A. Statutory Background

In 2009, Congress enacted the TCA to "provide authority to the [FDA] to regulate tobacco products under the [FD&C Act] by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products," and "to authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products," among other purposes. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009). Congress made 49 legislative findings in the Act, in which it acknowledged the "inherent dangerous[ness]" of tobacco products and nicotine and the strong public interest in regulating tobacco products and their advertising and promotion, and discussed Congress's interest in reducing youth tobacco use, in light of judicial findings that major U.S. tobacco companies specifically targeted and marketed their products to youth. TCA § 2. Congress further recognized that no other federal agency except the FDA "possesses the scientific expertise needed to implement effectively all provisions of the [TCA]." TCA § 2(45).

In light of those findings, the TCA authorized the Secretary of Health and Human Services to regulate the manufacture, distribution, and marketing of tobacco products. TCA § 901, codified at 21 U.S.C. § 387a (entitled "FDA authority over tobacco products"). The legislation immediately subjected "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" to a panoply of statutory and regulatory requirements, and also reserved future application of the TCA to "any other tobacco products that the Secretary [of Health and Human Services] by regulation *deems* to be subject to this chapter." 21 U.S.C. § 387a(b) (emphasis added). Congress defined "tobacco product" to mean "any product made or derived from tobacco

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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)." 21 U.S.C. § 321(rr)(1). The FDA's decision in 2016 to "deem" cigars and pipe tobacco as "tobacco products," and thus subject them to regulation, gave rise to this litigation.

B. Regulatory Background

1. The Cigar Product

Federal regulations define "cigar" to mean any "roll of tobacco that is wrapped in leaf tobacco or any substance containing tobacco" that is "not a cigarette." 21 C.F.R. § 1143.1. There are three major categories of cigar products: (1) little cigars, (2) cigarillos, and (3) traditional cigars. *See* Defs.' Cross-Mot. for Partial Summ. J. & Mem. in Support, ECF No. 74 [hereinafter Defs.' Cross-Mot.], at 6–7. Little cigars resemble cigarettes in size and tobacco content and thus "are positioned as cheaper substitutes for cigarettes." *See id.* at 7. Cigarillos are a shorter, slimmer version of traditional cigars and, generally speaking, contain between 3 and 10 pounds of tobacco per thousand units. *See id.* at 8. Traditional cigars are the largest cigar product, varying in length and diameter. *See id.* While little cigars and cigarillos are machine-rolled, traditional cigars may be either machine-rolled or hand-rolled. *See id.*

Within the category of traditional cigars are a sub-category known as "premium cigars." *See id.* Premium cigars typically are hand-rolled, made with a higher-grade tobacco, or are more expensive. *See id.* The term "premium cigar" is not, however, defined by federal statute or regulation. *See id.*

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2. The Existing FTC Health Warning Statements Regime

Long before the FDA's action in 2016, cigar products already were subject to some federal regulation. More than a decade earlier, in 2000, in settlements with the Federal Trade Commission ("FTC"), the seven largest U.S. cigar companies agreed to include warnings about significant adverse health risks on their packaging and advertisements. *See, e.g.*, Decision & Order, *In the Matter of Swedish Match N. Am., Inc.*, Docket No. C-3970 (F.T.C. Aug. 18, 2000), 2000 WL 1207446. The FTC settlements represented the first national requirements for health warnings on cigar products and applied to approximately 95 percent of the U.S. cigar market at the time. *See* Press Release, FTC, Nationwide Labeling Rules for Cigar Packaging and Ads Take Effect Today (Feb. 13, 2001), https://www.ftc.gov/news-events/press-releases/2001/02/nationwide-labeling-rules-cigar-packaging-and-ads-take-effect.

Pursuant to the consent orders, which remain in effect today, the covered cigar companies must display one of the five following health warning statements "clearly and conspicuously" on their advertising and packaging:

> SURGEON GENERAL WARNING: Cigar Smoking Can Cause Cancers Of The Mouth And Throat, Even If You Do Not Inhale.
>
> SURGEON GENERAL WARNING: Cigar Smoking Can Cause Lung Cancer And Heart Disease.
>
> SURGEON GENERAL WARNING: Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight.
>
> SURGEON GENERAL WARNING: Cigars Are Not A Safe Alternative To Cigarettes.
>
> SURGEON GENERAL WARNING: Tobacco Smoke Increases The Risk Of Lung Cancer And Heart Disease, Even In Nonsmokers.

See Decision & Order, *In the Matter of Swedish Match N. Am., Inc.*, 2000 WL 1207446, at *3. The FTC consent orders specify the size and formatting of the health warnings, and require that

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they appear on the principal display panel on cigar packages and be rotated at random on a 12-month basis. *See id.* at *4–7, *10–12.

Additionally, the FTC consent orders require the health warnings to appear on visual advertisements in a set-off, rectangular box to ensure that the warnings are readily visible and conspicuous. *Id.* at *5–8. For audio advertisements, the health warning statement must be delivered so that an ordinary consumer can hear and comprehend it. *Id.* at *8–9. Cigar companies also were required to submit for FTC approval, in advance of the consent orders' effective date, a plan for the rotation and display of the health warnings on cigar packages and advertisements. *Id.* at *11–12.

3. FDA Rules

a. The Deeming Rule

i. Proposed Rule

In the years following Congress's enactment of the TCA, cigar products were free from FDA regulation because cigars were not expressly listed in the Act's definition of "tobacco product." A harbinger of change arrived in the spring of 2014. On April 25, 2014, the FDA issued a Proposed Rule that would make, or "deem," cigars, pipe tobacco, and e-cigarettes subject to the TCA. *See Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23,142 (Apr. 25, 2014) ("Proposed Deeming Rule"). In the Proposed Deeming Rule, the FDA announced for consideration two options which "would provide two alternatives for the scope of the deeming provisions and, consequently, the application of the additional specific provisions." *Id.* at 23,143. Under Option 1, the FDA would deem all products

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meeting the statutory definition of "tobacco product"—including cigars and pipe tobacco—except accessories of deemed products to be subject to the TCA. *Id.* Under Option 2, the FDA would deem "only a subset of cigars" and "exclude from the scope of [the] proposed rule certain cigars that we refer to as 'premium cigars.'" *Id.* To effectuate this carve-out, Option 2 proposed a definition for "covered cigar" as:

> [A]ny cigar as defined in this part, except 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. at 23,150. The FDA noted that, while it had proposed a definition with respect to Option 2, it remained "concerned that any attempts to create a subset of premium cigars that are excluded from regulatory authority might sweep other cigar products under its umbrella." *Id.* The FDA therefore sought comment as to how to refine this definition, within the context of Option 2, "to ensure that the exclusion would apply only to those cigars that, because of how they are used, may have less of a public health impact than other types of cigars." *Id.*

The FDA sought comment on both options. Its purpose was "to determine whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars," as well as to determine the "relative merits of Option 1 versus Option 2, taking into account what is appropriate for the public health, including possible benefits to the public health or possible negative public health consequences of adopting one Option or the other." *Id.* at 23,143, 23,145. As to Option 2, the FDA noted that while "all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars

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may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation[,] and frequency of use by youth and young adults." *Id.* at 23,150. Plaintiffs and numerous other members of the public submitted detailed comments on the Proposed Deeming Rule.

ii. Final Rule

a. Health warning requirements

The FDA selected Option 1 and promulgated the final Deeming Rule on May 10, 2016, thus deeming all categories of cigars, including those referred to as "premium cigars," to be subject to the TCA. *See Final Rule Deeming Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974, 29,020 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) ("Deeming Rule"). In support of its decision, the FDA stated that it "concluded that deeming all cigars, rather than a subset, more completely protects the public health." *Id.* The FDA found that: "(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults." *Id.*

Under the Deeming Rule as originally announced, the newly deemed products would be subject to comparable TCA provisions and regulatory requirements to which cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were already subject. *Id.* at 28,976. These requirements include:

> (1) Enforcement action against products determined to be adulterated or misbranded (other than enforcement actions based on

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> lack of a marketing authorization during an applicable compliance period);
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> (2) Required submission of ingredient listing and reporting of [harmful and potentially harmful constituents];
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> (3) Required registration of tobacco product manufacturing establishments and product listing;
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> (4) Prohibition against sale and distribution of products with modified risk descriptors (e.g., "light," "low," and "mild" descriptors) and claims unless FDA issues an order authorizing their marketing;
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> (5) Prohibition on the distribution of free samples; and
>
> (6) Premarket review applications and approvals.

Id.

And there is more. The Deeming Rule also sets out comprehensive warning statement requirements, for both cigar product packaging and advertisements. By August 10, 2018, cigar product packages must display one of the six following health warning statements:

> (i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
>
> (ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
>
> (iii) WARNING: Cigars are not a safe alternative to cigarettes.
>
> (iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
>
> (v)(A) WARNING: Cigar use while pregnant can harm you and your baby.[3] . . .
>
> (vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

[3] This warning statement can be replaced with an optional alternative warning stating, "SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight." 21 C.F.R. § 1143.5(a)(1)(v)(B).

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21 C.F.R. § 1143.5(a)(1). These health warnings must be displayed on a rotating basis. *See id.* On cigar packages, each of the six health warning statements "must be randomly displayed in each 12-month period, in as equal number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed." *Id.* § 1143.5(c)(1). On cigar advertisements, the health warning statements "must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar." *Id.* § 1143.5(c)(2). Each cigar company must submit for FDA approval a plan for rotating warnings twelve months before advertising or commercially marketing a cigar product. *Id.* § 1143.5(c)(3).

The Deeming Rule also specifies the placement and size of the required health warnings. With respect to packaging, each warning statement must "appear directly on the package" and must be "located in a conspicuous and prominent place on the two principal display panels of the package," comprising "at least 30 percent of each of the principal display panels." *Id.* § 1143.5(a)(2). For cigars that are sold individually and not in a product package, the health warning statements must be posted at the retailer's point-of-sale on an 8.5 by 11-inch "clear, legible, and conspicuous" sign. *Id.* § 1143.5(a)(3). As to print and other visual advertisements, the warning statement must be located in the "upper portion of the area of the advertisement" and occupy "at least 20 percent of the area of the advertisement." *Id.* § 1143.5(b).[4]

These size mandates are more demanding than the size requirements under the FTC consent orders. According to Plaintiffs, the required package warnings are 195 to 237 percent larger on any one panel than under the FTC warnings scheme. And, when the Deeming Rule's additional

[4] The Deeming Rule imposes similar warning requirements on pipe tobacco packaging and advertisements. 81 Fed. Reg. at 29,060. Pursuant to 21 C.F.R. § 1143.3(a)(1), all pipe tobacco packages must display the following warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." The warning must occupy at least 30 percent of the two principal display panels. *Id.* § 1143.3(a)(2). On pipe tobacco advertisements, the warning must occupy at least 20 percent of the area of the advertisement. *Id.* § 1143.3(b)(1)–(2).

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requirement to cover a second display panel is included, Plaintiffs assert that the FDA's mandate covers approximately 390 to 475 percent more of a package's surface area than is required under the FTC's consent orders.

b. Related deemed products

In addition to cigars, pipe tobacco, and e-cigarettes, the Deeming Rule also deemed the "components or parts" of those newly deemed products to be subject to the TCA. The FDA defines the statutory term "component or part" to mean:

> [A]ny 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 product. Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102; 21 C.F.R. § 1100.3. Within the category of "component or part," the FDA included pipes used to consume pipe tobacco. 81 Fed. Reg. at 29,042.

Although it had the authority to do so, the FDA did not deem "accessories" of the newly deemed tobacco products subject to the TCA. The agency reasoned that "accessories, unlike components or parts, are expected to have little direct impact on the public health." *Id.* at 28,975. The FDA defined "accessories" to mean "any product" intended or reasonably expected to be used with or for the human consumption of a tobacco product, but not containing, made, or derived from, tobacco, that is: (1) "not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product," or (2) "intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product," but solely: (i) "controls moisture and/or temperature of a stored tobacco product," or (ii) provides an external heat source to initiate but not maintain combustion of a tobacco product." *Id.* at 29,102; 21 C.F.R § 1100.3. The FDA identified as examples of

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unregulated accessories items like "ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches," as well as "humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product." 81 Fed. Reg. at 28,975.

b. The User Fee Rule

To fund the regulation of tobacco products under the TCA, Congress requires the FDA to "assess user fees on, and collect fees from, each manufacturer and importer of tobacco products subject to this subchapter." *See* 21 U.S.C. § 387s. The user fees "are available only for the purpose of paying the costs of the activities of the [FDA] related to the regulation of tobacco products under . . . the [TCA]." *Id.* § 387s(c)(2).

When it promulgated the final Deeming Rule, the FDA simultaneously issued the User Fee Rule. Under that Rule, the FDA announced its intention to collect information from domestic manufacturers and importers of cigars and pipe tobacco in order to calculate the amount of user fees to be collected from these entities. *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 (May 10, 2016); 21 C.F.R. § 1150.5. Domestic manufacturers and importers of cigars and pipe tobacco were required to submit information to support the assessment of user fees to the FDA on August 20, 2016. 81 Fed. Reg. at 28,707; 21 C.F.R. § 1150.5. Because the FDA performs class allocations only on a full fiscal-year basis, domestic manufacturers and importers of cigars and pipe tobacco became subject to user fee assessments on October 1, 2016, the first full fiscal year following the User Fee Rule's effective date of August 8, 2016. 81 Fed. Reg. at 28,707.

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Notably, the User Fee Rule excluded from coverage other newly deemed products, such as e-cigarettes. The FDA explained that it lacked the statutory authority to impose user fees on any newly deemed products other than cigars and pipe tobacco. *See id.* at 28,711–12.

c. FDA's July 2017 Announcement of a "New Comprehensive Plan"

The presidential election of 2016 ushered in change to the FDA's approach to the Deeming Rule. On July 28, 2017, the FDA announced a "new comprehensive plan" for regulating tobacco products and nicotine. *See* Pls.' Mot. for Partial Summ. J., ECF No. 62 [hereinafter Pls.' Mot.], Ex. D, ECF No. 62-4 [hereinafter FDA Press Release]. In accordance with the plan, the FDA delayed implementation of some provisions of the Deeming Rule, but allowed others to go into effect. For instance, the agency extended until August 8, 2021, the compliance period for tobacco manufacturers to submit applications for newly deemed products that were on the market as of August 8, 2016. *See* Joint Status Report (dated Sept. 5, 2017), ECF No. 51 [hereinafter Sept. 5, 2017 JSR], ¶ 3; FDA Press Release. The health warning requirements, on the other hand, were left undisturbed.

The FDA also announced its intention to issue Advance Notices of Proposed Rulemaking ("ANPRM"). The contemplated rulemaking included a focus on the previous issue of whether to regulate premium cigars. An ANPRM, the FDA stated, would seek public comment on "the patterns of use and resulting public health impacts from premium cigars, which were included in the FDA's 2016 rule." FDA Press Release. Commenting on the FDA's "new comprehensive plan," Mitch Zeller, Director of the FDA's Center for Tobacco Products, explained: "Public input on these complex issues will help ensure the agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use." *Id.*

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d. Recent Regulatory Developments

In December 2017, the FDA formally announced its intention to initiate a rulemaking process focused on the question of premium cigars. *See* "Premium Cigars; Request for Scientific Information," *Agency Rule List - Fall 2017: Department of Health and Human Services*, Unified Agenda of Regulatory and Deregulatory Actions, OIRA, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AH88. The FDA observed that while it had received comments in response to the Proposed Deeming Rule "claiming that the health risks associated with cigar use generally, or with the use of premium cigars in particular were not significant because of the way such products are used," these comments ultimately failed to provide an adequate scientific basis for excluding those products from regulation. *Id.* The FDA therefore announced its intention to issue an ANPRM to request scientific information "that might support" exempting premium cigars from regulation or regulating them in a manner different from other cigars. *Id.*

The agency issued the ANPRM in late March 2018. *See* Defs.' Notice of Publication of ANPRM, ECF No. 91. It explained that in light of "the ongoing interest from many parties and sectors, such as industry and Members of Congress, in the regulatory status of premium cigars," the purpose of the ANPRM is "to request relevant new and different information, data, and analysis not submitted in response to FDA's proposed deeming rule . . . that could inform FDA's regulation of premium cigars." *See Regulation of Premium Cigars*, 83 Fed. Reg. 12,901, 12,902 (Mar. 26, 2018). Specifically, the FDA invited submission of comments, data, research results, and other information related to three topics: (1) the definition of premium cigars; (2) usage patterns of premium cigars; and (3) public health considerations associated with premium cigars. *Id.* at 12,903. The FDA also asked the public to submit studies or information regarding the Deeming

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Rule's current health warning statements, and requested comment on "whether any additional or alternative warning statements would be appropriate." *Id.* at 12,904.

C. Procedural Background

The Cigar Association of America, the International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America (collectively, "Plaintiffs") filed suit in this court, seeking declaratory, injunctive, and other relief from the Deeming Rule and challenging the legality of the User Fee Rule.

After Defendants filed their Answer, Plaintiffs filed an initial motion for summary judgment on February 13, 2017. Thereafter, the newly installed FDA administration signaled an openness to evaluating the agency's approach to aspects of the Deeming Rule. The parties accordingly requested multiple extensions of the briefing deadlines in order "to allow new leadership personnel at [HHS] to more fully consider the issues raised in [the] case and determine how best to proceed." Joint Mot. to Amend Scheduling Order (dated May 1, 2017), ECF No. 34, at 1. The court granted the requests, resulting in over four months of extensions. After the FDA's July 2017 announcement of its new comprehensive plan for the regulation of tobacco products, the parties sought one final 30-day extension of the briefing schedule. Joint Mot. to Amend Scheduling Order (dated Aug. 1, 2017), ECF No. 40, at 2–3. The court also granted this motion. Minute Order Aug. 7, 2017.

In a Joint Status Report dated September 5, 2017, the parties explained that, as a result of the FDA's announcement, they had agreed to defer resolution of certain of Plaintiffs' challenges to the Deeming Rule. Specifically, the parties agreed that Plaintiffs' challenges relating to the premarket review process, the FDA's decision to deem premium cigars subject to regulation, and the agency's cost-benefit analysis underlying the Deeming Rule—claims asserted in Counts I, IV,

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and V of Plaintiffs' Complaint—"should await the further regulatory action that the FDA has announced it intends to pursue, because those announced regulatory actions may materially change the regulatory scheme underlying these claims." Sept. 5, 2017 JSR at 2. The court agreed to defer resolution of those issues.

Other challenged aspects of the Rules remain unaffected by the agency's July 2017 announcement, *id.*, and as to those, Plaintiffs filed a new dispositive motion, this time only for partial summary judgment. Of the nine original counts in their Complaint, Plaintiffs presently seek summary judgment on six, asserting that: (1) the Deeming Rule's health warning statement requirements violate the TCA and the Administrative Procedure Act ("APA") (Count VI) and the First Amendment (Count VII); (2) the User Fee Rule's assessment of user fees on domestic manufacturers and importers of cigars and pipe tobacco, but not e-cigarettes, violates the APA (Count II) and the Fifth Amendment (Count III); (3) the Deeming Rule's treatment of retailers who blend pipe tobacco as "manufacturers" within the meaning of 21 U.S.C. § 387e violates the TCA and the APA (Count VIII); and (4) the Deeming Rule's classification of pipes as "components" of a tobacco product subject to regulation—rather than "accessories" not subject to regulation—violates the APA (Count IX). Compl. ¶¶ 100–60; Pls.' Mot. at 2–4; *see* Sept. 5, 2017 JSR at 3.

In addition, Plaintiffs moved for a preliminary injunction on their challenge to the Deeming Rule's health warnings mandates. *See* Pls.' Mot. for Prelim. Inj., ECF No. 61. The parties consented to consolidating the motion for preliminary relief with briefing on the merits. *See* Fed. R. Civ. P. 65(a)(2); Order Setting Summ. J. Schedule (dated Sept. 19, 2017), ECF No. 57.

III. LEGAL STANDARD

When reviewing an agency action under the APA, "summary judgment is the mechanism for deciding whether as a matter of law an agency action is supported by the administrative record

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and is otherwise consistent with the APA standard of review." *Louisiana v. Salazar*, 170 F. Supp. 3d 75, 83 (D.D.C. 2016) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971)). Pursuant to the APA, the court must uphold an agency's decision unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under the "narrow" arbitrary and capricious standard of review, the court may not "substitute its judgment for that of the agency," but must instead determine whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.* (*State Farm*), 463 U.S. 29, 43 (1983) (internal quotation marks omitted). An agency action is "arbitrary and capricious" and will be set aside if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

In reviewing an agency's interpretation of a statute it is charged with administering, courts apply the familiar two-step framework outlined in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984). Step one requires the court to determine, using "traditional tools of statutory construction," whether "Congress has spoken directly to the precise question at issue." *Id.* at 842. If Congress has so spoken, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 843 n.9. But if the statute remains ambiguous—meaning it "can be read more than one way," even after applying "traditional tools of statutory construction," *AFL-CIO v. FEC*, 333 F.3d 168, 172–73 (D.C. Cir. 2003)—or is silent on the question at hand, courts proceed to step two to determine "whether the

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agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. Judicial review at step two of *Chevron* is "highly deferential," *Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 667 (D.C. Cir. 2011), and the court must "accept the agency's [reasonable] construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation," *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

"In some circumstances, there is an overlap in the analysis required pursuant to *Chevron* Step Two[] and that required under the arbitrary and capricious standard" of the APA. *EchoStar Satellite LLC v. FCC*, 704 F.3d 992, 1001 (D.C. Cir. 2013) (internal citation omitted). Under *Chevron*'s second step, a court asks whether an agency's interpretation is "arbitrary or capricious in substance," *Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011), an inquiry that parallels the standard of review under the APA. "Ultimately, under either standard of review, the relevant question" in this case "is whether the FDA's decision represents the result of a reasonable exercise of its authority." *Amarin Pharm. Ireland Ltd. v. FDA*, 106 F. Supp. 3d 196, 206 (D.D.C. 2015).

IV. DISCUSSION

A. Health Warning Requirements

Plaintiffs' primary challenge is to the Deeming Rule's health warning requirements, which they assert violate the First Amendment, the TCA, and the APA. The court first assesses whether the Deeming Rule's health warning requirements run afoul of the TCA and the APA, and then turns to consider their constitutionality.

1. TCA and APA

Plaintiffs' TCA and APA challenges to the Deeming Rule's health warning requirements are two-fold. First, they assert that the agency failed to make the findings required by the TCA,

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21 U.S.C. § 387f(d)(1), to justify the warning requirements. And second, Plaintiffs contend that the agency violated the APA because it failed to explain why the existing FTC warning scheme was inadequate, opting instead to crowd out and restrict manufacturers' ability to communicate with consumers by imposing a requirement to cover 30 percent of two panels of a cigar box and 20 percent of any advertisement with warnings. The court rejects these arguments.

As to their first argument, Plaintiffs claim that the FDA made "no determination at all about the warnings' effect on decreasing cigar or pipe tobacco use," and thus failed to adhere to the statutory mandate provided by 21 U.S.C. § 387f(d)(1). Pls.' Mot. at 34. In pertinent part, that section of the TCA authorizes the FDA to "impose restrictions on the advertising and promotion of a tobacco product" "if the [agency] determines that such regulation would be appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). The agency's finding "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," and must take 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.* According to Plaintiffs, the agency did not assess whether the warnings would have any effect on decreasing cigar and pipe tobacco use, and even conceded that it could not make the statutorily-mandated finding. *See* Pls.' Mot. at 34 (citing A.R. 023973[5]).

Plaintiffs' contention is unavailing: The agency did make the required statutory findings. The FDA first connected the Deeming Rule as a whole to the public health standard, stating that it "believes that the sale and distribution restrictions the Agency is proposing," including the "health warning requirements," "meet the public health standard set forth in" 21 U.S.C. § 387f(d)(1).

[5] Citations to the Administrative Record can be found in the three-volume Joint Appendix, *see* ECF Nos. 81, 81-1, 81-2.

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79 Fed. Reg. at 23,146. The FDA specifically "concluded that the restrictions would be appropriate for the protection of the public health with respect to the risks and benefits to the population as a whole, including the increased likelihood that existing users will quit using tobacco products and the decreased likelihood that new users will initiate tobacco product use." *Id.* The agency made this statutory determination based on a the following factors: "available data on the addictiveness of nicotine" and nicotine's corresponding deleterious effects on the developing adolescent brain; the fact that newly deemed "combustible products like cigars, pipes, and waterpipes, are known causes of adverse health effects, including certain cancers and heart disease"; and evidence of the potential that users of the newly deemed products would migrate to cigarettes or other regulated products. *Id.* The agency explained that once finalized, the Deeming Rule's provisions "may lead to a decline in youth initiation for covered products" and "avert cigarette usage." *Id.* Failure to act and promulgate the Deeming Rule, according to the FDA, created the risk that such inaction would "reinforce consumers' existing confusion and misinformation about these products' safety or lack of harmfulness." *Id.* Thus, the agency made express findings connecting the Deeming Rule generally to the cessation and prevention of cigar and pipe tobacco use.

The FDA also made findings specific to the importance and efficacy of the health warnings. Under sections titled "Effectiveness of Warnings" and "Proposed Addictiveness Warning" in the Proposed Deeming Rule, the agency observed: (1) "The use of tobacco packages to help consumers better understand and appreciate tobacco-related health risks has a number of advantages"; (2) "Requiring health warnings in advertisements similarly is an important means of helping consumers better understand and appreciate the health consequences of tobacco use"; (3) "FDA believes that the proposed warnings will be effective in helping consumers better

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understand and appreciate critical information"; (4) "Research has shown that using the largest possible lettering can increase warning effectiveness and increasing font size aids communication"; (5) "The content of the proposed messages also indicates that they should help consumers understand and appreciate the health risks"; and (6) "The absence of a health warning requirement for other tobacco products could reinforce the existing false sense of security that youth have about the safety of those products." *Id.* at 23,164–65. In making these findings, the FDA cited both academic studies and international protocols showing that the increased size of warnings improves noticeability and reader recall. *See id.* It also referenced studies concerning the content of the proposed messages, and explained why the proposed warnings were likely to be more effective. *See id.* at 23,165. The FDA reiterated and incorporated these findings in the final Deeming Rule. *See, e.g.*, 81 Fed. Reg. at 29,064 ("FDA agrees that health warnings are an effective means to help consumers understand and appreciate the risks of using tobacco products."); *see also id.* at 28,982, 28,988–89, 29,060–73.

Notwithstanding what is plain on the record, Plaintiffs contend that these findings are insufficient for a host of reasons. First, Plaintiffs fault the FDA for making the statutorily required findings only in the Proposed Deeming Rule, and not the final version. Pls.' Reply in Supp. of Pls.' Mots. for a Prelim. Inj. & Partial Summ. J., ECF No. 78 [hereinafter Pls.' Reply], at 30. But that is incorrect. Not only does the final rule expressly incorporate the findings from the Proposed Deeming Rule, *see* 81 Fed. Reg. at 29,062, but the agency also responded to comments questioning the need and efficacy of warning requirements, and it rejected those views, *see id.* at 29,063. Accordingly, the agency's findings are adequately reflected in the record after the public had the opportunity of notice and comment.

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Second, Plaintiffs assert that FDA "merely mouths the words of the statute, eschews any serious analysis, and hedges its language." Pls.' Reply at 30. But that contention also is misplaced, as both the Proposed Deeming Rule and the final Deeming Rule contain multiple pages devoted to "the effects of larger health warnings on cigars and pipe tobacco," which Plaintiffs claim is lacking, *id.* *See* 81 Fed. Reg. at 28,982, 28,988–89, 29,060–73; 79 Fed. Reg. at 23,146, 23,162–70. Thus, FDA did more than simply regurgitate the statutory text.

Next, Plaintiffs assert that FDA itself conceded the lack of connection between the required health warnings and the likelihood of reducing cigar and pipe tobacco use, when it admitted that "there has not yet been extensive research regarding the effectiveness of health warnings on tobacco products other than cigarettes." 79 Fed. Reg. at 23,165. But as Defendants explain, that excerpt, derived from the agency's Regulatory Impact Analysis, addresses the agency's inability to *quantify* the benefits of the Deeming Rule's warning requirements prior to their implementation date. The agency did not concede, as Plaintiffs insist, the absence of any connection between health warnings and reducing and discouraging cigar and pipe tobacco use.

In any event, the relative absence of such studies is not fatal. "It is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion." *State Farm*, 463 U.S. at 52. That is precisely what the agency did here. It extrapolated from its experience with other tobacco products—particularly cigarettes—to reach its determination that the health warnings are appropriate for the public health and likely to affect cigar and pipe tobacco usage, as required by 21 U.S.C. § 387f(d)(1). *See, e.g.*, 79 Fed. Reg. at 23,165 ("FDA believes that the fundamental similarities between cigarettes and smokeless tobacco and other tobacco products allow for the application of data regarding the effectiveness of cigarette and smokeless tobacco

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warnings to warnings for other tobacco products."); *id.* ("Although there has not yet been extensive research regarding the effectiveness of health warnings on tobacco products other than cigarettes, *existing studies support the use of these messages*." (emphasis added) (citations omitted)). Thus, the agency's determination that health warnings will likely reduce and prevent cigar and pipe tobacco use, despite limited research studies specific to those newly deemed products, was not arbitrary and capricious.

Finally, Plaintiffs maintain that the "agency cannot seriously contend . . . that quantitative data was beyond its grasp," as it "had *sixteen years* and an entire nation's worth of data to examine the efficacy of the FTC warnings." Pls.' Reply at 31. Plaintiffs, however, have identified no requirement, statutory or otherwise, that compelled the FDA to undertake such studies to make the findings required by 21 U.S.C. § 387f(d)(1). *Cf. Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008) ("[I]n the absence of available evidence, Congress does not require the agency to conduct its own studies."). Plaintiffs' TCA challenge to the health warning requirements therefore fails.

Plaintiffs' APA challenge to the warning requirements suffers the same fate. To the extent Plaintiffs suggest that the warnings mandate violates the APA because the agency failed to make the requisite findings under 21 U.S.C. § 387f(d)(1), the court rejects the argument for the reasons already stated. Plaintiffs offer two other arguments under the APA. First, they assert that the Deeming Rule's health warning requirements are arbitrary and capricious because the agency failed to consider, as an alternative, adopting the existing FTC scheme already in place for much of the cigar industry, which would have been less costly and less burdensome to integrate. And, second, they argue that the warning requirements placed on the cigar industry are disproportionately more onerous than those placed on the cigarette industry, even though the FDA

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has determined that cigarettes occupy "the most dangerous end of the risk continuum." Pls.' Mot. at 36. Neither argument is convincing.

As to Plaintiffs' first argument, the court takes issue with the notion that the "baseline" for warning statements on cigar packaging and advertising *begins* with the FTC warning scheme. Plaintiffs cite no case requiring one agency to use as its starting point restrictions adopted by another agency, especially when the other agency's restrictions arose not from rulemaking but from a consent agreement with the regulated parties and, importantly, do not cover all regulated products. In that respect, this case differs materially from *State Farm*, relied upon by Plaintiffs. There, the agency failed to consider, without explanation, an alternative regulatory approach, which the agency itself previously had endorsed as a way of achieving regulatory objectives. *See State Farm*, 463 U.S. at 48. Here, by contrast, the alternative endorsed by Plaintiffs—the FTC consent orders—was the result of another agency's enforcement action and compromise and pre-dates the Deeming Rule by nearly fifteen years. *State Farm* therefore did not compel the FDA to take as its starting point the FTC warnings scheme.

In developing its own cigar warnings regime, the FDA was well within its discretion to look elsewhere. Primarily, the FDA considered the congressional mandates of the TCA itself and the World Health Organization Framework Convention on Tobacco Control ("FCTC"), to which the United States is a signatory. The Deeming Rule's warning scheme is comparable to both. Under the TCA, Congress established for smokeless tobacco warning sizes of at least 30 percent of the packaging's two principal panels, and at least 20 percent of the area for each advertisement. 15 U.S.C. § 4402(a)(2)(A), (b)(2)(B). The mandated warning sizes for cigarette packaging and advertising is even larger: 50 percent of the front and rear panels of cigarette packaging and 20 percent for advertising. *Id.* § 1333(a)(2), (b)(2). In addition, the FCTC, to which the United

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States became a signatory in May 2004, recommends a warning size of "50% or more of the principal display areas" and "no less than 30% of the principal display areas." World Health Organization, WHO Framework Convention on Tobacco Control, art. 11.1.b.iv (2003). It was perfectly reasonable for the FDA to rely on consensus- and evidence-based reference points for its own rulemaking in lieu of the FTC's warnings regime. *See* 81 Fed. Reg. at 29,066 (considering but rejecting the FTC's warning scheme in favor of health warnings "similar to the requirements for smokeless products and similar to those suggested by [the WHO's Framework Convention]"); *see also id.* at 29,064 (citing cohort study finding, AR 18757–64, that after the UK enhanced its textual health warnings to meet the minimum FCTC standard, "UK smokers were more likely to think about quitting, to think about the health risks of smoking, and to be deterred from having a cigarette compared to smokers in Australia and the United States where smaller warnings did not conform to FCTC standards").

Plaintiffs' additional contention that the cigar warning regime is disproportionately more demanding than the required scheme for cigarettes, and therefore arbitrary and capricious, also is not well taken. The congressionally mandated sizes of warnings for cigarette packaging is actually *greater* than for cigar products. *See* 15 U.S.C. § 1333(a)(2), (b)(2). Granted, those warning requirements were not yet in effect at the time the FDA finalized the Deeming Rule, *see* 81 Fed. Reg. at 28,988, but that fact does not render the agency's decision to impose *smaller* labeling requirements on cigar products arbitrary and capricious.[6]

[6] Plaintiffs also make several arguments under the APA regarding the FDA's alleged failure to properly consider the costs of regulation. *See* Pls.' Mot. at 35; Pls.' Reply at 31. As Plaintiffs have not fully developed those arguments, they are better left to consider with Plaintiffs' claim that the FDA failed to carry out a proper cost-benefit analysis in violation of the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995 (Count IV). That claim is not—per the parties' agreement—before the court.

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In sum, because the Deeming Rule's health warning requirements satisfy the TCA and the APA, the court continues on to consider Plaintiffs' constitutional challenges.

2. First Amendment Challenges

Count VII of Plaintiffs' Complaint alleges that the Deeming Rule's health warning and advertising disclosure requirements violate the First Amendment. Compl. ¶¶ 142–48. In their partial summary judgment motion, Plaintiffs assert that the Rule's warnings scheme violates the First Amendment for two reasons: (1) increasing the size of the new health warnings unconstitutionally restricts speech by "crowding out" manufacturers' and retailers' ability to communicate with consumers, and (2) requiring manufacturers and retailers to submit a warning rotation plan to the FDA before they can communicate with consumers constitutes an unconstitutional prior restraint on speech. Pls.' Mot. at 16. The court rejects the first contention as without merit, and does not reach the second because Plaintiffs did not raise a prior-restraint claim in their Complaint.

a. Commercial Speech

Plaintiffs' challenge to the Deeming Rule's warning requirements presents the following issue: Whether a warning statement of the size required by the FDA—comprising 30 percent of the principal panels of a cigar product package and 20 percent of a cigar product advertisement—infringes Plaintiffs' commercial speech rights under the First Amendment. Plaintiffs assert that the Deeming Rule is unconstitutional because it unjustifiably and dramatically increases the size of health warnings already required by the FTC consent orders on cigar packages and advertisements, thereby crowding out and restricting the space available to manufacturers and retailers to communicate with consumers. Defendants counter that the Deeming Rule does not restrict the speech of cigar manufacturers or retailers, but instead merely requires Plaintiffs to make

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accurate health-related disclosures reasonably aimed at "help[ing] consumers better understand and appreciate the risks and characteristics of tobacco products," and does not otherwise impose an undue burden, and thus falls well within the limits of the First Amendment. *See* Defs.' Cross-Mot. at 19 (quoting 81 Fed. Reg. at 28,981).

As a threshold matter, the parties agree that the warning requirements imposed by the Deeming Rule impact only commercial speech, that is, "expression related solely to the economic interests of the speaker and its audience." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561 (1980). Although commercial speech enjoys First Amendment protection, it is well established that such protection is "less extensive than that afforded 'noncommercial speech.'" *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 637 (1985). Therefore, there is no contention here that the Deeming Rule's warning mandates are subject to strict scrutiny.

The parties' threshold dispute instead centers on, if not strict scrutiny, then which constitutional test to apply. Plaintiffs maintain that the warning requirements should be assessed under the intermediate scrutiny standard set forth in *Central Hudson*, the case that typically governs "First Amendment questions arising in the arena of commercial speech." *See United States v. Philip Morris USA Inc.*, 855 F.3d 321, 327 (D.C. Cir. 2017) (internal quotation marks omitted). For a government restriction on commercial speech to survive intermediate scrutiny under *Central Hudson*, it must "directly advance a substantial governmental interest and be no more extensive than is necessary to serve that interest." *Millavetz, Gallop & Millavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (alterations and internal quotation marks omitted). The government can establish that its regulation "directly advances" the state interest involved by

providing evidence of the measure's effectiveness. *See Am. Meat Inst. v. U.S. Dep't of Agric.* (*AMI*), 760 F.3d 18, 26 (D.C. Cir. 2014) (citing *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993)).

Defendants, on the other hand, argue that the Deeming Rule's warning requirements should be analyzed under the more "relaxed standard of review" set forth in *Zauderer v. Office of Disciplinary Counsel*. *Zauderer* applies "when the government uses a disclosure mandate to achieve a goal of informing consumers about a particular product trait," provided "that the reason for informing consumers qualifies as an adequate interest." *AMI*, 760 F.3d at 26. To withstand scrutiny under *Zauderer*, the disclosure requirements need only be "reasonably related to the [government's] interest," and not so "unjustified or unduly burdensome" as to chill protected commercial speech. *See* 471 U.S. at 651.

Zauderer's more relaxed standard recognizes that there are "material differences between disclosure requirements and outright prohibitions on speech," which, in the commercial speech context, warrant corresponding levels of scrutiny. *Id.* at 650. In *Zauderer*, the Supreme Court declined to apply *Central Hudson*'s intermediate scrutiny to analyze a state disciplinary rule requiring attorneys advertising their contingent-fee rates also to disclose that clients would remain responsible for litigation costs. *Id.* Observing that the rule required the disclosure of "purely factual and uncontroversial information" about contingent-fee arrangements, the court reasoned that the state was not seeking "to prevent attorneys from conveying information to the public" but instead "requir[ing] them to provide somewhat more information than they might otherwise be inclined to present." *Id.* In such circumstances, the Court concluded, government regulation is assessed under a reasonableness test. *Id.* at 651. The Court explained that, "because the extension of First Amendment protection to commercial speech is justified principally by the value to

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consumers of the information such speech provides, [an advertiser's] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id.*

i. The Applicable Constitutional Test

The challenged provisions of the Deeming Rule require disclosures, but not every disclosure regime is subject to *Zauderer*'s reasonableness standard. *Zauderer* applies only to disclosures of "purely factual and uncontroversial information about the good or service being offered." *AMI*, 760 F.3d at 27 (internal quotation marks omitted). The court therefore must first determine whether the disclosures are "purely factual" and "uncontroversial."

Though the D.C. Circuit has been less than clear in "defin[ing] [the] terms ['purely factual' and 'uncontroversial'] precisely," *see Nat'l Ass'n of Mfrs. v. SEC* (*NAM*), 800 F.3d 518, 528 (D.C. Cir. 2015), at a minimum, "a disclosure requirement is 'purely factual' when there is no dispute about factual accuracy," *see Kimberly-Clark Corp. v. District of Columbia*, 286 F. Supp. 3d 128, 140 (D.D.C. 2017) (citing *AMI*, 760 F.3d at 27). In *Zauderer*, for instance, the "purely factual" disclosure was that clients in a contingent-fee arrangement with an attorney would still have to pay costs, even if their lawsuit was unsuccessful; there was no dispute that such statement was accurate. 471 U.S. at 651; *see also AMI*, 760 F.3d at 27 (observing no dispute regarding whether country-of-origin labeling requirements qualify as "purely factual," where "the facts conveyed are directly informative of intrinsic characteristics of the product"). The same is true here. Plaintiffs do not assert that the warning statements are anything but "purely factual."

Moving on, the determination of whether these "purely factual" warning statements are "uncontroversial" poses a different inquiry than mere factual accuracy. *See NAM*, 800 F.3d at 528 ("'[U]ncontroversial as a legal test . . . must mean something different than 'purely factual.'"). A disclosure is "controversial," the court gathers, when it is "subject to misinterpretation by

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consumers," or "inflammatory." *RJ Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1217 (D.C. Cir. 2012), *overruled on other grounds by AMI*, 760 F.3d at 22. In *RJ Reynolds*, the D.C. Circuit considered whether proposed graphic-image warnings for cigarette packages constitute the type of "purely factual and uncontroversial" information that triggers review under *Zauderer*. 696 F.3d at 1216. Among other images, one proposed warning depicted a man smoking through a tracheotomy hole. *Id.* Though the FDA claimed that the image symbolized the addictive nature of cigarettes, the court concluded that the image would more logically be misinterpreted by consumers to suggest that a tracheotomy is a common consequence of smoking. *Id.* Other "inflammatory" images—including depictions of a woman crying and a small child—failed to convey any warning information about cigarettes at all, and therefore also fell outside the ambit of *Zauderer*. *Id.* at 1216–17. Plaintiffs do not challenge the warnings at issue here as "controversial" or "inflammatory." Nor, it seems, could they reasonably do so. The textual warnings about the health consequences of cigar use are unambiguous and unlikely to be misinterpreted by consumers.

Although Plaintiffs do not dispute that the Deeming Rule requires display of only "purely factual and uncontroversial information," and thus do not challenge the "criteria triggering the application of *Zauderer*," *AMI*, 760 F.3d at 27, they nonetheless maintain that *Central Hudson*'s intermediate scrutiny should apply. In Plaintiffs' view, the sheer size, format, and duplication of the warnings required by the Deeming Rule transforms the Rule from a compelled disclosure to a restriction of speech governed by *Central Hudson*. As Plaintiffs point out, the D.C. Circuit has observed that *Zauderer* contemplated a line where "the compulsion to speak becomes more like a speech restriction than a disclosure." *Pursuing America's Greatness v. FEC*, 831 F.3d 500, 507 n.3 (D.C. Cir. 2016); *see also id.* ("[I]n some instances compulsion to speak may be as violative of the First Amendment as prohibition on speech." (quoting *Zauderer*, 471 U.S. at 650)). The

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FDA crossed that line here, say Plaintiffs, by "assault[ing] . . . customers' senses" with "blaring government pronouncements" on advertisements, Pls.' Reply at 6, and imposing on the historically "distinctive, artistic, aesthetically pleasing" cigar packaging the jarring juxtaposition of the warning statements in black, bold font on a white background. Pls.' Mot. at 17. Stated differently, Plaintiffs claim that the warnings here are so large and "glaring" as to obscure industry players' messaging and overtake their ability to communicate with their customers. *Id.* at 18.

The court is unpersuaded. The court has had the benefit of viewing samples of cigar packaging integrating the mandatory warning statements. It may be true, as Plaintiffs contend, that the Deeming Rule's requirements demand "large[r] and stark[er]" warnings on packaging than those required under FTC consent orders, Pls.' Reply at 5, and that the FDA's regime compels use of a larger percentage of advertisements, *see id.* at 6. But even so, cigar manufacturers and retailers retain sufficient space in which to communicate their messaging: 70 percent of cigar packages and 80 percent of advertisements remain unencumbered and available for speech. Simply put, the Deeming Rule does not impose the "type of restriction—an outright ban on advertising . . .—[that] would properly be analyzed under the heightened *Central Hudson* standard of scrutiny." *See Dwyer v. Cappell*, 762 F.3d 275, 284 (3d Cir. 2014). In the end, what Plaintiffs find most objectionable is that the Deeming Rule "require[s] them to provide somewhat more information"—or, as more apt here, larger text on a greater surface area—"than they might otherwise be inclined to present." *Zauderer*, 471 U.S. at 652. Their corresponding First Amendment interests therefore are "substantially weaker than those at stake when speech is

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actually suppressed.'" *Id.* at 651 n.14. In such circumstances, the court is bound to apply the laxer standard of *Zauderer*.

Plaintiffs offer no convincing case law to persuade the court otherwise. Plaintiffs' citation to *Dwyer v. Cappell*, does not advance their cause. *See* Pls.' Mot. at 18; Pls.' Reply at 5; *cf.* Transcript of Oral Arg. Hr'g, ECF No. 85 [hereinafter Hr'g Tr.], at 9–10 (Plaintiffs' counsel admitting that there is no case that applies *Central Hudson* to a disclosure requirement). There, the New Jersey Supreme Court approved an attorney guideline prohibiting attorneys from advertising using complimentary quotations from judicial opinions, unless the full text of the judicial opinion appeared in full. *Dwyer*, 762 F.3d at 278. Observing that the challenged guideline "bears characteristics" of both a disclosure requirement and a restriction on speech, the Third Circuit ultimately opted to analyze the disclosure requirement under *Zauderer*, not *Central Hudson*. And, applying *Zauderer*, the court found the full-opinion disclosure requirement unduly burdensome and thus struck down the rule. *Id.* at 282–84. Thus, although *Dwyer* helps Plaintiffs in one sense—an example of a case invalidating a disclosure requirement even under *Zauderer*'s more lenient standard—it does not help them establish that *Central Hudson* is the appropriate test here.

Having concluded that *Zauderer*'s test is the correct one to apply in this case, the court now turns to assess whether the Deeming Rule's health warning statement requirements withstand scrutiny under that decision.

ii. Application of *Zauderer*

Under *Zauderer*, a "purely factual" and "uncontroversial" disclosure requirement satisfies the First Amendment so long as it is (1) "reasonably related" to the government's interest and (2) not "unjustified or unduly burdensome." 471 U.S. at 651. Plaintiffs argue that the Deeming

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Rule fails to satisfy even this "relaxed standard." They identify what they contend are three fatal flaws. First, they maintain that the government has not identified a "substantial" government interest that can sustain the Deeming Rule's disclosure requirement. Second, Plaintiffs assert that the warning statement disclosures are not reasonably related to any government interest. And, finally, Plaintiffs argue that the warning statements are so large and conspicuous as to be unduly burdensome. The court rejects each argument.

a. Defendants have identified a substantial government interest.

In applying *Zauderer*, the court's first task is to assess the adequacy of the government interest motivating the health warning requirements scheme. *See AMI*, 760 F.3d at 23.[7] Whether *Zauderer* requires the government to articulate a "substantial" government interest, as Plaintiffs contend, *see* Pls.' Reply at 20, is an open question in this Circuit. *See AMI*, 760 F.3d at 23. This court need not delve into that issue here, however, because the FDA has identified a substantial government interest: To "'help consumers better understand and appreciate the risks and characteristics of tobacco products'" and "to help correct current misperceptions about the newly deemed products." Defs.' Cross-Mot. at 19 (quoting 81 Fed. Reg. at 28,981); *see* 79 Fed. Reg. at 23,166 ("FDA proposes to help consumers better understand and appreciate the addictiveness of tobacco product use by adding warnings on packages and in advertisements . . . ."); *see also* 79 Fed. Reg. at 23,163 ("The purpose of health warnings is to help current and potential tobacco users understand and appreciate the serious adverse health consequences associated with tobacco product use and the addictive nature of tobacco products."). In identifying this interest, the agency relied on evidence establishing widespread misperceptions regarding the true health hazards of

[7] Plaintiffs suggest only half-heartedly that the *Zauderer* standard does not apply because the analysis in *Zauderer* is limited to compelled disclosures designed to prevent the deception of consumers. Pls.' Mot. at 28 n.7. But, as they concede, this limited view of *Zauderer* was rejected by the *en banc* D.C. Circuit in *AMI*. *See* 800 F.3d at 520.

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cigars and demonstrating that cigar smokers mistakenly believe that cigars are less addictive, more natural, and less harmful than cigarettes. Defs.' Cross-Mot. at 19 (quoting A.R. 986–87, 7708). That is true among both youth and adults. In short, there is ample record evidence to support the FDA's determination that there exists a need to educate the public about the health risks associated with cigar and pipe tobacco use.

The conclusion that the FDA's stated interest qualifies as "substantial" is well-rooted in precedent. In *Rubin v. Coors Brewing Co.*, the Court considered whether a ban on placing alcohol content on beer labels violated brewers' commercial speech rights. 514 U.S. 476, 478 (1995). Although the Court ultimately struck down the alcohol-content restriction under *Central Hudson* because it failed to advance a government interest in a direct and material way, *see id.*, the Court did find the government's stated interest to be substantial. The court held: "[T]he Government here has a significant interest in protecting the health, safety, and welfare of its citizens by preventing brewers from competing on the basis of alcohol strength, which could lead to greater alcoholism and its attendant social costs. Both panels of the Court of Appeals that heard this case concluded that the goal of suppressing strength wars constituted a substantial interest, and we cannot say that their conclusion is erroneous." *Id.* at 485; *cf. Edenfield*, 507 U.S. at 769 (recognizing that the government has a substantial interest in "ensuring the accuracy of the commercial marketplace"). Consistent with *Rubin*, the D.C. Circuit has recognized that the "government has a substantial interest in 'promoting the health, safety, and welfare of its citizens.'" *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (quoting *Rubin*, 514 U.S. at 485). In *Pearson*, the Circuit held that, in defending regulations that required sellers of dietary supplements to obtain agency authorization before labeling such supplements with "health claims," the FDA had articulated a substantial interest in "protection of public health." *Id.* at 655–

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56. The court perceives little difference in the interest approved in *Pearson* and the FDA's stated interest here to supply the public with accurate warnings about the health risks of using the newly deemed products.

The reasoning of *AMI* is also instructive. There, the D.C. Circuit recognized as substantial the government's interest in country-of-origin labeling on meat cuts based on a number of factors: the "context and long history" of such disclosures; the consumer interest in extending such labeling to food products; and the "individual health concerns and market impacts that could arise in the event of a food-borne illness outbreak." 760 F.3d at 23. As in *AMI*, "several aspects" of the government's interest in this case "combine to make the interest substantial." *See id.* For instance, health warning requirements similarly have a long history, having been imposed on tobacco products by Congress since 1965. *See* Defs.' Cross-Mot. at 21. And "health concerns" also are necessarily implicated by the government's goal, as there is no dispute that "tobacco products are dangerous to health when used in the manner prescribed." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 135, 161 (2000). If the government's interest in country-of-origin labeling is a substantial one, surely the same is true of health warnings on packages and advertising of cigar and pipe tobacco products.

Notwithstanding the foregoing legal landscape, Plaintiffs vigorously assert that the FDA's stated interest in informing the public about the adverse health consequences associated with tobacco use, "standing alone," does not constitute a substantial government interest. Pls.' Mot. at 19; Pls.' Reply at 20–21. Citing the Supreme Court's decision in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), and the D.C. Circuit's decision in *RJ Reynolds v. FDA*, 696 F.3d at 1205,[8]

[8] The D.C. Circuit in *AMI* overruled *RJ Reynolds* to the extent that it "may be read as . . . limiting *Zauderer* to cases in which the government points to an interest in correcting deception." *AMI*, 760 F.3d at 22–23. The undisturbed *Central Hudson* analysis in *RJ Reynolds* therefore remains precedential.

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Plaintiffs maintain that a rule restricting speech of tobacco manufacturers and retailers must be tied to the objective of "reduc[ing] youth use of tobacco products." Pls.' Mot. at 20. But neither case establishes such a categorical rule. The Supreme Court in *Lorillard* did recognize the government interest in "preventing underage tobacco use" to be a substantial, if not compelling one, but at no point did the Court identify it to be the *only* cognizable interest the government can assert when imposing a disclosure requirement on tobacco products. *See* 533 U.S. at 564. And, in *RJ Reynolds*, although the D.C. Circuit observed that it was "skeptical" that the government's interest in discouraging consumers from purchasing a lawful product could be substantial, it ultimately assumed an interest in reducing smoking rates is substantial, observing that the Supreme Court had previously implied the significance of such an interest. *See* 696 F.3d at 1218 n.13 (citing *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161). Nowhere did the Circuit say that *only* the reduction of youth consumption of tobacco products can constitute a substantial government interest under the First Amendment.

Plaintiffs alternatively maintain that the asserted government interest here merely aims to improve "information" and "consumer understanding," Pls.' Mot. at 20; Pls.' Reply at 9, and therefore is disqualified as a substantial government interest by the D.C. Circuit's decision in *RJ Reynolds* and the Second Circuit's reasoning in *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996). The court disagrees with Plaintiffs' reading of both cases.

In *RJ Reynolds*, the D.C. Circuit held that an FDA rule requiring cigarette packages to bear certain graphic warnings violated the First Amendment. 696 F.3d at 1208. There, the FDA's "*only* explicitly asserted interest [during the rulemaking process] [was] an interest in reducing smoking rates." *Id.* at 1218. Applying *Central Hudson*, the court held that the FDA had "not provided a shred of evidence" showing that the graphic warning requirements "directly advance" the

government interest in reducing smoking rates. *Id.* at 1219. When FDA offered, as an alternative, a substantial interest in "effectively communicating health information regarding the negative effects of cigarettes," the court rejected it. *Id.* at 1221. The attempt to "reformulate its interest as purely informational," the court explained, "is unconvincing, as an interest in 'effective' communication is too vague to stand on its own." *Id.* Instead, the court observed, "FDA's interest in 'effectively communicating' the health risks of smoking 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.* (emphasis added).

The interest asserted by the agency in the Deeming Rule does not suffer from the same defect. Here, the FDA's stated interest is in actually communicating health risks to the public, not "effectively" communicating them, as in *RJ Reynolds*. That distinction is critical. The FDA's stated interest in this case is a decidedly an objective one: To provide accurate information and to correct documented, widespread misperceptions about the health risks of cigar use. *See, e.g.*, A.R. 7708. Therefore, the concern that the court in *RJ Reynolds* expressed—that an indeterminate interest in "effective communication" would allow the government to define its goal however it saw fit, 696 F.3d at 1221—is not present here. Additionally, the FDA in this case does *not* assert, as it did with respect to the graphic warnings in *RJ Reynolds*, that the particular formatting specifications it selected here constitute, in and of themselves, a substantial government interest. Rather, the FDA has consistently characterized the warnings' formatting specifications as a *means* by which to "accomplish its goal" of providing accurate health information to the public, *id*. *See, e.g.*, 81 Fed. Reg. at 29,065 ("FDA believes that the prescribed format of the health warnings will be effective in helping consumers better understand and appreciate the risks of these products."); *id.* ("FDA believes that the size of the warnings will be effective in helping consumers better

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understand and appreciate the critical information presented by the health warning."). In that sense, the FDA's position here presents no conflict with *RJ Reynolds*.

Nor is the interest asserted by the FDA anything like the interest rejected as insufficient in *International Dairy Foods*. There, the only government interest offered to sustain a Vermont law requiring dairy manufacturers to label milk from cows treated with a growth hormone was a "strong consumer interest and the public's 'right to know.'" *Int'l Dairy Foods*, 92 F.3d at 73. Indeed, the state of Vermont expressly disclaimed that "health or safety concerns prompted the passage" of the labeling law, likely because the record contained "no scientific evidence from which an objective observer could conclude that [the growth hormone] has any impact at all on dairy products." *Id.* Observing that Vermont "could not justify the statute on the basis of 'real' harms," the court concluded that the state's interest—which amounted to mere "consumer curiosity"—was "not a strong enough state interest to sustain the compulsion of even an accurate, factual statement." *Id.* at 73–74. By contrast, there can be no dispute that the Deeming Rule's warning requirements can be justified on the basis of real, substantiated harms caused by cigar use. Far from satisfying mere curiosity, the information disclosed by the Deeming Rule "bears on a reasonable concern for human health or safety." *See id.* at 74. *International Dairy Foods* therefore demands no different conclusion than that the government interest animating the Deeming Rule's health warning statement requirements is a substantial one.

b. The Deeming Rule's warning requirements are reasonably related to the government's substantial interest.

Having established that the interest identified by the government to sustain the Deeming Rule is substantial, the court moves on to consider whether the warning requirements are

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"reasonably related" to the government's interest.[9] Applying *Zauderer*, the warning statement requirements readily pass muster.

Unlike *Central Hudson*'s intermediate scrutiny—where the commercial speech restriction would have to be shown to "directly and materially advance the asserted governmental interest," *see Lorillard*, 533 U.S. at 555 (alteration omitted)—*Zauderer* employs "less exacting scrutiny," *Milavetz*, 559 U.S. at 249. Whereas the government would have to provide evidence of a measure's effectiveness to satisfy *Central Hudson*, "such evidentiary parsing is hardly necessary" under *Zauderer*. *AMI*, 760 F.3d at 26. For this reason, the court again rejects Plaintiffs' complaint that the FDA did not examine whether the existing FTC warning scheme was insufficient to communicate health risks of cigars before promulgating the Deeming Rule. *Zauderer*—and likely even *Central Hudson*—does not require such an inquiry. *See Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 557 (6th Cir. 2012) ("[C]onstitutionality under [*Zauderer*] does not hinge upon some quantum of proof that a disclosure will realize the underlying purpose. A common-sense analysis will do. And the disclosure has to advance the purpose only slightly." (citing *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001))); *cf. AMI*, 760 F.3d at 25 (observing that *Central Hudson* requires only that the government "show a 'reasonable fit' or a 'reasonable proportion' between means and ends" (citations omitted)).

In view of the record evidence, academic studies, *see, e.g.*, A.R. 5144–50, 5290–99, 18745–55, 18756–64, and international consensus, 81 Fed. Reg. at 28,988–89—all supporting the

[9] Plaintiffs have attached to their briefing three declarations of Cecil R. Reynolds, Ph.D. in order to undermine the FDA's record evidence. *See* Pls.' Mot., Attach. 27, ECF No. 62-27; Pls.' Mot., Attach. 30, ECF No. 62-30; Pls.' Reply, Attach. 8, ECF No. 78-8; *see also* Pls.' Reply at 15 n.7. Under the APA, "review is to be based on the full administrative record that was before the [agency] at the time [it] made [its] decision." *Am. Wildlands*, 530 F.3d at 991 (quoting *Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 420). Accordingly, the court will "not allow parties to supplement the [administrative] record unless they can demonstrate unusual circumstances justifying a departure from this general rule." *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010). Plaintiffs have not shown that the declarations satisfy the "unusual circumstances" here, as "they merely disagree with the [FDA's] conclusions," *see Am. Wildlands*, 530 F.3d at 1002, and the court therefore disregards Plaintiffs' extra-record submissions.

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commonsense notion that "[u]sers are more likely to recall warnings that are a larger size and that appear on the front/major surfaces of the tobacco product package," *id.* at 28,989—the court concludes that the size, format, and other design features of the warning statements are reasonably related to the government's goal of providing accurate information about, and curing misperceptions regarding, the health consequences of cigar use. Stated simply, providing accurate warnings about the health risks of cigar use in a size, format, and manner that consumers will readily notice and retain satisfies the "means-end fit" requirement under *Zauderer*. *See AMI*, 760 F.3d at 26 ("To the extent that the government's interest is in assuring that consumers receive particular information . . ., the means-end fit is self-evidently satisfied when the government acts only through a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered." (internal quotation marks omitted)).

c. The Deeming Rule's warning requirements are not "unduly burdensome."

Finally, the court considers whether the Deeming Rule's warning requirements are so "[u]njustified or unduly burdensome" as to "chill[] protected speech." *See Milavetz*, 559 U.S. at 250 (internal citation omitted); *AMI*, 760 F.3d at 27 ("*Zauderer* cannot justify a disclosure so burdensome that it essentially operates as a restriction on constitutionally protected speech."). Plaintiffs charge that the Deeming Rule's warnings are so large and so costly that they are "unduly burdensome." Pls.' Reply at 21.[10] The court disagrees.

Plaintiffs claim that the size of the mandated warnings will drown out their speech. To that end, they cite a number of decisions from other circuits striking down commercial speech

[10] Any suggestion by Plaintiffs that the Deeming Rule's application to advertisements beyond print and visual advertisements is "unduly burdensome"—including radio or broadcast advertisements—is premature. The FDA

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disclosures that were too burdensome to be constitutional. But those cases are simply not like this one. For example, in *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), the Seventh Circuit refused to apply *Zauderer* to analyze the State of Illinois' requirement that video game retailers place a four square-inch sticker stating "18" on any "sexually explicit video game." *Id.* at 643, 652. In applying strict scrutiny instead, the court reasoned that the "18" sticker—"unlike a surgeon general's warning of the carcinogenic properties of cigarettes"—"communicates a subjective and highly controversial message" that precluded application of *Zauderer*. *Id.* at 652–53. The court ultimately concluded that the four square-inch sticker—when imposed on a 7.5-inch by 5.5-inch DVD box—was not "narrowly tailored" to the State's goal of informing parents about the sexually explicit content in games. *See id*. *Entertainment Software*'s analysis and holding thus does not disturb the court's conclusion here, as the speech restriction in that case was considered under a stricter standard of review.

Tillman v. Miller, 133 F.3d 1402 (11th Cir. 1998) (per curiam), is likewise distinguishable. There, the Eleventh Circuit held unconstitutional a Georgia law requiring any television advertisement soliciting the filing of workers' compensation claims or encouraging consultation of an attorney, medical provider, or clinic with regard to a workers' compensation claim, to contain a five-second on-screen notice "in boldface Roman font 36 point type" warning about criminal and financial penalties for making a false workers' compensation claim. *Id.* at 1403–04 n.1. As did the district court it was reviewing, the Eleventh Circuit centered its conclusion that the requirement was "too burdensome" on the fact that the disclosure was "not tied to an inherent

explained in the Deeming Rule that it "intends to provide guidance on how to comply with the health warning requirements on unique types of media" and clarified that the formatting requirements of 21 C.F.R. §§ 1143.3(b)(2) and 1143.5(b)(2) apply only to print and visual advertisements. 81 Fed. Reg. at 29,064. Until such guidance is issued, the court is not in a position to assess whether the disclosures would be unduly burdensome as to those types of advertisements.

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quality of the thing [the plaintiff lawyer] is trying to sell—his legal services." *Id.*; *see Tillman v. Miller*, No. 95-cv-1594, 1996 WL 767477, at *5 (N.D. Ga. Sept. 30, 1996) (holding Georgia law "unduly burdensome" under *Zauderer* and reasoning that "[w]hile the compelled speech is related to the general subject matter of the targeted advertisements—workers[']compensation claims—it is wholly unconnected to the factual substance in the advertisements it targets. The compelled speech has no nexus with the terms of the services advertised"). Here, by contrast, the warnings are "tied to an inherent quality of the thing [Plaintiffs] [are] trying to sell." There can be no logical argument that the compelled warning statements are unconnected to the advertisements and packaging of the tobacco products that would bear them. Accordingly, because the agency is not seeking to impose on Plaintiffs any unrelated disclosure statements, *Tillman*'s reasoning is inapposite.[11]

This case differs from others cited by Plaintiffs in another critical respect: The disclosures required by the Deeming Rule are not so lengthy or cumbersome as to effectively rule out speech or "nullify" the message meant to be communicated. Requirements that an attorney include the full text of a judicial opinion on a law firm website instead of quoting excerpts of that opinion, *see Dwyer*, 762 F.3d at 275; that a Certified Financial Planner and Certified Public Accountant seeking to identify her credentials in advertisements include a disclaimer "stating that the recognizing agency is not affiliated with or sanctioned by the state or federal government," and setting out the agency's "requirements for recognition, including . . . education, experience, and testing," *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146–47 (1994); and that an attorney advertisement include "at least all of the following information": (1) the lawyer's name and office

[11] Plaintiffs also rely on *American Beverage Ass'n v. City and County of San Francisco*, 871 F.3d (9th Cir. 2017), to bolster their argument that the Rule is "unduly burdensome." But, the Ninth Circuit recently voted to rehear that case en banc, rendering the three-judge panel disposition non-precedential. *See Am. Beverage Ass'n v. City and Cty. of San Francisco*, 880 F.3d 1019, 1020 (9th Cir. 2018) (granting rehearing en banc).

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location, (2) a client's responsibility for costs, (3) all jurisdictions in which the lawyer is licensed, (4) the use of simulated scenes or pictures or actors portraying clients, and (5) the use of a spokesperson, whether the spokesperson is a lawyer, and whether the spokesperson is paid, *Pub. Citizen Inc. v. La. Attorney Disciplinary Bd.*, 632 F.3d 212, 229 (5th Cir. 2011), all involve disclosure regimes that impose a burden far greater than what the Deeming Rule requires. Unlike in those instances, cigar manufacturers and importers can still effectively communicate their desired message—whether that be the sense of the product's "luxury and distinction" through its "designs, symbols, and trademarks" or information about the product's "country of origin, seed varietal, [or] process of manufacture," Pls.' Mot. at 17—on the remaining 70 percent of cigar packaging and 80 percent of cigar advertisements. Stated differently, because the desired messaging is not "effectively ruled out" by the Deeming Rule's warning statement requirements, the Rule is not unduly burdensome under *Zauderer*. Nor is the Rule unduly burdensome because its mandates "chill[] protected commercial speech." *Zauderer*, 471 U.S. at 651; *see also AMI*, 760 F.3d at 27. Indeed, nowhere do Plaintiffs assert that the size of the warnings will dampen the industry's enthusiasm to engage in commercial speech or cause manufacturers or importers to pull products from the marketplace.

So, to sum up the foregoing analysis: Because the warning statements are factual and uncontroversial disclosures aimed at informing the public about the risks of cigar and pipe tobacco use and at correcting the public's misperceptions about such products' use, and because the Rule

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does not impose these requirements in an "unjustified or unduly burdensome" manner, the Rule is constitutional under *Zauderer*.

b. Prior Restraint

Plaintiffs also challenge the warnings scheme as an unconstitutional prior restraint on speech because it impermissibly compels manufacturers and retailers "wishing to speak with consumers" to submit a warnings rotation plan to the FDA in advance and wait for the FDA's approval before they can so speak. Pls.' Mot. at 16. The court does not reach this challenge, however, because Plaintiffs failed to raise it in their Complaint. And, despite the court's suggestion at oral argument, Hr'g Tr. at 31, Plaintiffs have not filed a motion to amend the Complaint to add a prior restraint claim.

"It is well established that a party may not amend its complaint or broaden its claims through summary judgment briefing." *District of Columbia v. Barrie*, 741 F. Supp. 2d 250, 263 (D.D.C. 2010); *see also Sloan ex rel. Juergens v. Urban Title Servs., Inc.*, 652 F. Supp. 2d 51, 62 (D.D.C. 2009) (citing cases). This principle applies equally in cases, like this one, that raise constitutional challenges to an agency action. *See, e.g.*, *Zarmach Oil Servs., Inc. v. U.S. Dep't of Treasury*, 750 F. Supp. 2d 150, 159 (D.D.C. 2010) (holding that the Fourth Amendment challenge, "having been raised for the first time in plaintiff's opposition," was not properly before the court). The proper course for a plaintiff who seeks to add or broaden a claim is through a motion to amend under Rule 15(a). *Barrie*, 741 F. Supp. 2d at 264.

Plaintiffs' Complaint, even generously read, does not contain a challenge to the Deeming Rule's warning plan submission requirement as an unconstitutional prior restraint on speech. Count VII of Plaintiffs' Complaint—styled as "Violation of the First Amendment to the U.S. Constitution: The Final Rule's Warning Label Requirements Impermissibly Restrict Free

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Speech"—consists of allegations that pertain solely to Plaintiffs' claim that the warning label and advertising disclosure requirements infringe Plaintiffs' First Amendment commercial speech rights. *See* Compl. at 35–36. Nowhere in the Complaint do Plaintiffs mention the warning plan submission requirement, nor do the words "prior restraint" or something similar appear. Moreover, although the Complaint generally requests "a declaration that FDA's Final Rule establishing warning label requirements for cigars violates the First Amendment to the U.S. Constitution and should be set aside," Compl. ¶ 148, the specific relief sought is tied to the Deeming Rule's warning statement requirements: (1) vacatur of the Final Rule under the APA "for imposing warning label formats on cigars in excess of the FTC Consent Decree's requirements without justification"; and (2) a declaration that the Final Rule "imposing warning label format requirements on cigars in excess of those contained in FTC Consent Decree[s] violate the First Amendment," *see id.* at 38 ¶¶ e–f. The Prayer for Relief does not include an express plea to vacate the Deeming Rule's plan submission requirement. *See id.*

Finally, and perhaps most tellingly, Plaintiffs did not brief a prior restraint claim when they filed their initial motion for summary judgment. In that motion, filed before the parties agreed to narrow the issues for partial summary judgment briefing, Plaintiffs moved for judgment as to *all* claims asserted in their Complaint. *See generally* Pls.' Mot. for Summ. J., ECF No. 22; *cf.* Pls.' Mot. at 13 (describing their initial motion for summary judgment as "exhaustive" and relating to "all claims"). Nowhere, however, does that motion assert that the Deeming Rule's rotation-plan submission requirement constitutes an unconstitutional prior restraint on speech. Plaintiffs' silence in their initial dispositive motion is strong evidence that they themselves did not understand their Complaint to contain a prior restraint challenge.

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Accordingly, as Plaintiffs do not sufficiently raise an unconstitutional prior restraint challenge in their pleading, the court does not reach that question.

c. The FDA's announced rulemaking concerning premium cigars

Although the court holds that the Deeming Rule's health warning mandates do not violate the APA, the TCA, or the First Amendment, the court cannot let pass without comment what it "deems" to be a grossly unfair exercise of agency authority. The health warning requirements have an effective date of August 10, 2018. In the lead up to that date, the cigar industry has expended millions of dollars in designing and creating new, conforming packaging—a fact that the FDA does not contest. However, months *before* the effective date's arrival, the FDA issued an ANPRM, "seeking comments, data, results or other information that may inform regulatory actions FDA might take with respect to premium cigars." 83 Fed. Reg. at 12,901. Some of the information the ANPRM seeks directly concerns the health warnings mandate. For example, the ANPRM asks for "[s]tudies or information on the required warning statements, . . . which will be required to appear on cigar packaging and advertising in the near future." *Id*. at 12,904. The agency also seeks studies or information regarding "consumer perceptions of the health risks of premium cigars when compared to other tobacco products, including cigars," and "consumer perceptions of the addictiveness of premium cigars, especially compared and contrasted with perceptions for other cigars." *Id.* In total, the ANPRM seeks no less than *two dozen* categories of comments, data, or other information concerning the definition, usage patterns, and public health implications of premium cigars. The sheer breadth of the ANPRM begs the obvious question: Might the FDA in the near future do away with the health warning requirements for premium cigars? And yet another: Why is the agency insisting that the premium cigar industry expend millions of dollars to conform to regulatory mandates that might be rescinded only months after

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their effective date? The FDA provides no satisfactory response to either question. Whatever the answers, one thing is certain: Requiring the premium cigar industry to incur substantial compliance costs while the agency comprehensively reassesses the wisdom of regulation, *before* the warnings requirements go into effect, smacks of basic unfairness. In the court's view, the prudent course would be for FDA to stay the warnings requirement as to premium cigars.

The court's displeasure with the FDA's handling of the status of premium cigars, no doubt, provides little consolation to the industry. But the court can do no more. Its hands are tied by both the law and the posture of the case.

There is nothing inherently unlawful about an agency's decision to reconsider the wisdom of a regulation, even before it goes into effect. An agency is free to change its mind about an existing policy, "either with or without a change in circumstances." *State Farm*, 463 U.S. at 57 (citation omitted); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016). Nor is an agency's present willingness to consider new information necessarily an indictment of its past decision-making. As the D.C. Circuit recently observed: "[A] change in an agency's course in reaction to new information does not indicate that its initial course was necessarily arbitrary and capricious when charted." *New Eng. Power Generators Ass'n v. FERC*, 879 F.3d 1192, 1201 (D.C. Cir. 2018). That is arguably what is occurring here. The ANPRM reaffirms that, at the time of the original rulemaking, there was a lack of evidence to justify differential treatment for premium cigars. 83 Fed. Reg. at 12,902 (explaining that "comments against regulation [of premium cigars] provided little data to support the opinions expressed and, where studies were submitted, provided little information about the studies cited"). The ANPRM also seeks only "new and different information, data, and analysis not submitted in response to FDA's proposed deeming rule." *Id.* By so limiting the scope of the information and comments requested,

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the FDA does not concede, or even hint, that the prior rulemaking record was deficient in any respect. Nor does the ANPRM affirmatively state or suggest that the regulatory regime *will change* as to premium cigars. Rather, properly viewed, it is "no more than a broadly stated request for information and comment." *P&V Enters. v. U.S. Army Corps of Eng'rs*, 516 F.3d 1021, 1024 (D.C. Cir. 2008). Thus, the agency's decision here to re-analyze the status of premium cigars, even before the warning requirements go into effect, is not "smoking gun" evidence of prior arbitrary and capricious rulemaking.

The court's power to act is limited in yet another way. The present posture of this case does not offer a basis on which to enjoin enforcement of the Deeming Rule's warning requirements during the pendency of the FDA's newly announced rulemaking process. The court already has rejected Plaintiffs' statutory and constitutional challenges to the warning requirements, so the court has found no violation to be remedied. Additionally, Plaintiffs agreed to defer litigating their claim under the APA that the FDA's decision not to adopt "Option Two," i.e., the option that would have excluded premium cigars from regulation, was itself arbitrary and capricious (Count V). *See* Joint Status Report (dated Sept. 8, 2017), ECF No. 53, ¶ 4. Therefore, there is no claim presently before the court that contests the agency's basis for subjecting premium cigars to regulation in the first instance.

Nor have Plaintiffs made a different challenge, namely to the FDA's refusal to stay the warnings requirement as to premium cigars during the pendency of the present rulemaking process. *See* Pls.' Resp. to Defs.' Notice of Publication of ANPRM, ECF No. 92, at 1 (expressing surprise that the decision to issue the ANPRM "was not accompanied by voluntary stay of enforcement of the mandated warnings provision"); *cf. Clean Air Council v. Pruitt*, 862 F.3d 1, 6–7 (D.C. Cir. 2017) (holding that agency's decision to stay implementation of a rule and thus "relieve[] regulated

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parties of any obligation to meet the . . . deadline" was a reviewable "final agency action"). The agency has delayed implementing regulations in seemingly similar circumstances. For instance, the FDA decided to delay other aspects of the Deeming Rule in July 2017 when it announced its intention to engage in rulemaking, and "to begin a public dialogue," concerning lowering nicotine levels in combustible cigarettes to non-addictive levels through product-standard setting. *See* FDA Press Release (announcing delay of deadline to submit tobacco product review applications for newly regulated tobacco products to "afford the agency time to explore clear and meaningful measures to make tobacco products less toxic, appealing[,] and addictive"). Yet, it did not do the same for premium cigars during the newly announced rulemaking process. *Cf. Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005) ("An agency must provide an adequate explanation to justify treating similarly situated parties differently."). The court cannot, however, remedy a perceived wrong unless it is presented for consideration, and Plaintiffs have not challenged this differential treatment.

In the end, even if fundamental fairness strongly favors a stay for premium cigars during the just-initiated rulemaking process, regrettably neither the law nor the posture of this case allows for such judicial relief.

B. User Fee Rule

When the FDA promulgated the Deeming Rule, it contemporaneously promulgated the User Fee Rule pursuant to its authority under the TCA. *See* 21 U.S.C. § 387s(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 387a(b) of this title *or is deemed by the Secretary in a regulation* under section 387a(b) of this title[.]" (emphasis added)). Plaintiffs do not challenge the FDA's decision to assess user fees on domestic manufacturers and importers of cigars and pipe tobacco in order to fund the

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FDA's regulation of tobacco products. Instead, they challenge the FDA's decision *not* to assess user fees on e-cigarettes, another newly deemed tobacco product. According to Plaintiffs, this "selective implementation of a user fee" is unlawful for three reasons. Pls.' Mot. at 40. First, they assert that the FDA incorrectly concluded that it did not have statutory authority to impose user fees on e-cigarettes under the TCA. Second, they argue that charging only some newly deemed products impermissibly imposes a "tax," rather than a user fee. Finally, Plaintiffs contend that the selective imposition of the User Fee Rule violates the Fifth Amendment of the U.S. Constitution.

The court concludes that the FDA's decision not to impose the User Fee Rule on e-cigarettes is compelled by statute and, even if the statute were ambiguous or silent, is a reasonable interpretation of the TCA deserving of deference. Additionally, the court rejects Plaintiffs' characterization of the user fee as a "tax," along with Plaintiffs' contention that imposing the User Fee Rule only on some newly "deemed" products violates the Fifth Amendment. Plaintiffs' challenge to the User Fee Rule therefore fails.

1. Chevron *Analysis*

The question whether the FDA's decision to impose user fees on cigars and pipe tobacco but not e-cigarettes is consistent with the TCA requires analysis under *Chevron*'s two-step framework.

a. Step One

At step one of *Chevron*, the court asks if Congress has spoken directly to the precise question at issue—here, whether the FDA can assess user fees on only some of the newly deemed tobacco products—by employing "traditional tools of statutory construction," including "examination of the statute's text, legislative history, and structure, as well as its purpose." *Bell Atl. Tel. Co. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997). To prevail at step one, Plaintiffs must

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show "that the statute unambiguously forecloses the agency's interpretation." *Catawba Cty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009).

The TCA provides that the FDA "shall in accordance with [21 U.S.C. § 387s] assess user fees on, and collect such fees from, each manufacturer and importer of tobacco product subject to [subchapter IX]." 21 U.S.C. § 387s(a). "[E]ach manufacturer and importer of tobacco product" subject to subchapter IX includes the original classes of tobacco products listed in § 387a(b). *Id.* ("This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter."). The statute further sets forth the total amount of user fees authorized to be assessed and collected by the FDA each fiscal year, *id.* § 387s(b)(1),[12] and, critically, expressly identifies the classes of tobacco products that shall share in the total collection: "cigarettes," "cigars (including small cigars and cigars other than small cigars)," "snuff," "chewing tobacco," "pipe tobacco," and "roll-your-own tobacco," *id.* § 387s(b)(2). The pro rata assessment for each class is calculated by multiplying "the applicable percentage of each class [of tobacco product] for the fiscal year"—a percentage determined under the Fair and Equitable Tobacco Reform Act of 2004 ("FETRA")—by the total amount of user fees to be assessed and collected. *Id.* § 387s(b)(2)(B) (incorporating 7 U.S.C. § 518d(c)). The cross-referenced section of FETRA, in turn, sets out percentage allocations for the exact same six classes of tobacco products listed in § 387s; these allocations total 100 percent. *See* 7 U.S.C. § 518d(c)(1).[13] The percentage share of

[12] For example, for fiscal year 2017, the "total amount of user fees authorized to be assessed and collected" is $635,000,000, and for fiscal year 2018, is $672,000,000. 21 U.S.C. § 387s(b)(1)(I)–(K).

[13] FETRA allocates assessments among classes of tobacco products as follows: (1) 96.331 percent for cigarette manufacturers and importers; (2) 2.783 percent for cigar manufacturers and importers; (3) 0.539 percent for snuff manufacturers and importers; (4) 0.171 percent for roll-your-own tobacco manufacturers and importers; (5) 0.111 percent for chewing tobacco manufacturers and importers; and (6) 0.066 percent for pipe tobacco manufacturers and importers. 7 U.S.C. § 518d(c)(1)(A)–(F).

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the user fees assessment for each manufacturer or importer within each of the six classes is likewise determined under FETRA, 21 U.S.C. § 387s(b)(4), and is based on each manufacturer's or importer's share of gross domestic volume,[14] *see* 7 U.S.C. § 518d(e)–(h).

Plaintiffs' step one argument relies on their reading of Section 387s(a), which requires FDA to assess user fees on "*each* manufacturer and importer of tobacco products subject to this subchapter." 21 U.S.C. § 387s(a) (emphasis added). Plaintiffs read the term "each" to mean that Congress intended that *all* deemed products are subject to user fees, not just those listed in Section 387s(b)(2)(B), e.g., cigars and pipe tobacco. Plaintiffs also point to another clause, Section 387s(b)(2)(B)(iii), which provides that "no user fees shall be assessed on a class of tobacco products" other than those listed in section 387a(b)—the originally regulated "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," plus those deemed by the FDA to be subject to subchapter IX. Taken together, Plaintiffs contend, those sections compel the interpretation that *all* products so deemed, including e-cigarettes, must be assessed user fees.

Plaintiffs' interpretation cannot, however, be squared with a plain reading of the statute. Section 387s(a) provides that user fees must be assessed "in accordance *with this section*." *See* 21 U.S.C. § 387(s)(a) (emphasis added). The "section" itself does not expressly provide an allocation among classes of tobacco products, but instead, in a subsection titled "[a]llocations," states that "[t]he applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under" FETRA "for each such class of product for such fiscal year." *Id.* § 387s(b)(2)(B)(ii). Two features of this provision are noteworthy. The first is that the provision refers to the applicable percentages for the classes of tobacco products

[14] The term "gross domestic volume" means the volume of tobacco products "removed" and not exempt from excise taxes under the Internal Revenue Code. 7 U.S.C. § 518d(a)(2).

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"described in clause (i)." "[C]lause (i)" "describes" only six classes of tobacco products; it does not contemplate an allocation for any newly deemed products, unless among the listed six. The second critical feature is that the allocation among the enumerated six classes of tobacco products is supposed to be done in the manner Congress set forth in FETRA. FETRA in turn identifies the same six classes of tobacco products named in "clause (i)," or Section 387s(b)(2)(B)(i), and it too does not contemplate an allocation for any product other than the listed six. The percentages specified in FETRA for each of the six classes total 100 percent. *See supra* n.13. Thus, to harmonize these provisions, the user fees assessed under the TCA among the six tobacco products listed in "clause (i)" must be allocated using the FETRA percentages, up to 100 percent. Any other reading would not "be in accordance with this section." 21 U.S.C. § 387s(a). Plaintiffs offer no satisfactory explanation as to how, consistent with the TCA's directions, the agency could reduce the pro rata share of each of the six listed tobacco products to create a seventh share for e-cigarettes (or an eighth share for other newly deemed products, and so on) or how such a re-allocation would be determined.[15] *See* 7 U.S.C. § 518d(c)(1); 81 Fed. Reg. at 28,709. The FDA's interpretation of the TCA's user fees provision therefore is the natural one, and is not foreclosed by Plaintiffs' contrary reading.

Stifled by the statutory text, Plaintiffs resort to policy arguments to support their reading. They contend that Congress could not have intended to allow newly deemed tobacco products, like e-cigarettes, to become a free rider in funding the TCA's regulatory scheme. As Plaintiffs put it: "There is no provision in the statute for regulating a class of tobacco products and requiring other classes of products to pay the necessary costs of such regulation." Pls.' Reply at 34. That

[15] Plaintiffs suggest that the FDA could use product equivalencies to assist in calculating user fees for e-cigarettes, asserting that "FDA itself identified metrics in its response to comments." Pls.' Reply at 36. But FDA only repeated a metric suggested by a commenter, and rejected the use of any metric as contrary to the TCA. *See* 81 Fed. Reg. at 28,712.

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argument is not without some force. After all, it does seem unfair that a newly deemed product increasingly used among youth and adults alike does not have to pay its fair share. *See generally Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 394 (D.D.C. 2017) (citing agency findings regarding the rise in e-cigarette use among middle and high school students and adults). But the argument ultimately proves unpersuasive. The agency cannot legislate when Congress has clearly spoken. This is an area better left for Congress to consider in the first instance.

In sum, the statute plainly provides that if one day deemed to be "tobacco products" by the FDA, "cigars" and "pipe tobacco" "shall" be subject to user fees to fund the statutory scheme. 21 U.S.C. § 387s(b)(2)(B). The text, however, contains no such mandate with regard to e-cigarettes, despite evidence that Congress was aware of their existence at the time it passed the TCA. *See* Defs.' Reply in Supp. of Cross-Mot., ECF No. 80, at 20 (citing 155 Cong. Rec. H6626 (June 12, 2009)). The statutory text could be no clearer: The agency was compelled to assess user fees only on the six classes of tobacco products enumerated in the statute.

b. Step Two

In the court's view, the plain text of the TCA mandates the assessment of user fees only on those enumerated classes of tobacco products. But, even assuming that the plain text of the TCA does not unambiguously compel the FDA's interpretation, and proceeding to *Chevron*'s second step, the court holds, for the reasons stated above, that the FDA has offered in the User Fee Rule a "reasonable explanation of how its interpretation serves the statute's objectives." *Nat'l Ass'n of Broads. v. FCC*, 789 F.3d 165, 175 (D.C. Cir. 2015). The court therefore defers to the agency's interpretation.

When promulgating the final User Fee Rule, the FDA addressed public comments asserting that the agency was required by statute to assess fees on all deemed tobacco products, including

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those outside the six classes. 81 Fed. Reg. at 28,709–14. In its responses, the FDA explained its belief that assessing user fees on classes of tobacco products beyond the six listed in the TCA and FETRA was prohibited by the text of the statute, but also explained that even if the statute were silent or ambiguous, its interpretation was a reasonable one. *Id.* at 28,711–12. Moreover, in response to comments arguing that the FDA abandon the tax-based methodology from FETRA altogether, or even adopt a metric proposed by the public, the FDA explained that it was interpreting the text to prohibit the assessment of user fees on any class of tobacco products beyond the six listed in the TCA in part because:

> [I]t is reasonable to conclude that Congress did not intend FDA to develop a new system that departs from the methodology mandated by FETRA. Any such system would necessarily be subjective, especially relative to the system Congress established for the enumerated six classes. As such, FDA's interpretation is a reasonable construction of the [TCA].

Id. at 28,712. In light of the FDA's reasonable—and in the court's view, compelled—interpretation of the statute, the court concludes that the User Fee Rule is entitled to deference.

2. The User Fees Are Not a "Tax"

Plaintiffs' assertion that the uneven application of the User Fee Rule imposes a "tax" on the tobacco products assessed is readily dismissed. The court understands Plaintiffs to argue that, by excepting e-cigarette makers from paying a user fee, the FDA is not imposing on other tobacco products a "user fee," as that term is commonly understood, but instead a "tax," which the FDA does not have the authority to impose. According to Plaintiffs, a "user fee" is: "(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." Pls.' Mot. at 42 (citing *Nat'l Cable Television Ass'n, Inc. v. United States*, 415 U.S. 336, 340-41 (1974); U.S. Gov't Accountability Office, GAO-08-386SP, Federal User Fees: A Design Guide 4-5 (2008)). A "tax," on the other

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hand, is "an enforced contribution to provide for the support of government." *United States v. La Franca*, 282 U.S. 568, 572 (1931). By allowing e-cigarettes to "free ride," yet be subject to FDA regulation, Plaintiffs say that they are paying the equivalent of a tax, not a user fee.

The court disagrees. In light of the court's conclusion above that Congress expressly intended that only the six classes of tobacco products enumerated in the statute be assessed user fees to pay for the FDA's regulation of tobacco products, the User Fee Rule does no more than that commanded by Congress. No general definition of "user fee" can compel the agency to do otherwise. That Congress chose not to include a mechanism to re-calculate the pro rata share formula to take account of newly deemed products, like e-cigarettes, does not turn the user fee into a "tax." *Cf. United States v. Sperry Corp.*, 493 U.S. 52, 60 (1989) ("This Court has never held that the amount of a user fee must be precisely calibrated to the use that a party makes of Government services."). Plaintiffs' argument is therefore unpersuasive.

3. The User Fee Rule Does Not Violate the Fifth Amendment

Characterizing the User Fee Rule as "naked economic favoritism," Plaintiffs lodge a constitutional challenge to the Rule under the equal protection component of the Due Process Clause of the Fifth Amendment. Pls.' Mot. at 43. Applying rational-basis review to the economic classification challenged here, as Plaintiffs concede is appropriate, *see Sperry Corp.*, 493 U.S. at 65, the User Fee Rule readily satisfies the Constitution.

Applying rational-basis review, the User Fee Rule is constitutionally valid if "there is a plausible policy reason for the classification, the legislative facts on which the classification is apparently based rationally may have been considered to be true by the governmental decisionmaker, and the relationship of the classification to its goal is not so attenuated as to render the distinction arbitrary or irrational." *Armour v. City of Indianapolis*, 566 U.S. 673, 682 (2012)

(citation omitted). A "plausible reason" for an economic classification exists if there is "any reasonably conceivable state of facts that could provide a rational basis for the classification." *Id.* (citation omitted). In this case, the burden rests on Plaintiffs as "the one[s] attacking the legislative arrangement to negative every conceivable basis which might support it." *Id.* at 685 (citation omitted).

The Supreme Court's decision in *United States v. Sperry Corp.* is on point. There, the Court upheld the constitutionality of a statute requiring the Federal Reserve Bank of New York to deduct and pay into the U.S. Treasury a percentage of any award made by the Iran-U.S. Claims Tribunal in favor an American claimant. 493 U.S. at 54. Assessing the Due Process Clause challenge to the statute, the court applied rational-basis review and readily concluded that the statute's assessment of a user fee against successful claimants, rather than all claimants, passed muster. *Id.* at 65–66. In so holding, the Court provided justifications Congress "*could have*" relied on in imposing the user fees on only one class of persons. *Id.* at 65 (emphasis added). In finding that there were a number of rational grounds on which the statute could have rested, the Court noted that the case was unlike one "where the Court was unable to discern any legitimate interest that was served" by an economic classification. *Id.*

As in *Sperry*, there are a number of rational reasons that could explain why Congress opted to limit the FDA to assessing user fees on the enumerated six classes of tobacco products. For example, Congress reasonably could have determined that novel, newly deemed products, like e-cigarettes, were unlikely to overcome the market shares of the traditional enumerated products, and so it left for another day the question of how to account for a novel newly deemed product if it gained sufficient market share. Or, Congress could have decided that incorporating the FETRA scheme—and its readily available data—was the best way to assess user fees, as manufacturers

and importers already were providing information and paying fees pursuant to FETRA. The court therefore can discern rational interests served by the TCA's user fee scheme.

Although Plaintiffs invite the court to second-guess Congress's determination to assess user fees only on six classes of tobacco products, rational-basis review "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices." *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993); *see also Armour*, 566 U.S. at 685 ("[T]he Constitution does not require the [government] to draw the perfect line nor even to draw a line superior to some other line it might have drawn. It requires only that the line actually drawn be a rational line."). The basis for the User Fee Rule's classification between the six classes of tobacco products and any others is rational; the court therefore concludes that the User Fee Rule does not violate the Fifth Amendment.

C. Designation of Retail Establishments That Blend Pipe Tobacco as "Manufacturers" Subject to 21 U.S.C. § 387e

Plaintiffs next challenge the Deeming Rule's designation of tobacco retailers who blend pipe tobacco in-store as "manufacturers" within the scope of 21 U.S.C. § 387e.[16] *See* 81 Fed. Reg. at 29,004 (requiring that "persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco . . .) . . . register with FDA and submit product listings under" 21 U.S.C. § 387e); 81 Fed. Reg. at 29,049 (explaining that retail establishments that blend pipe tobacco "are subject to and must comply with all applicable statutory and regulatory requirements for 'tobacco product manufacturers'"). Section 387e lays out who must register with the FDA, 21 U.S.C.

[16] At oral argument, Plaintiffs clarified that their argument with respect to blenders of pipe tobacco is that the FDA has wrongly subjected them to the requirements of Section 387e. *See* Hr'g Tr. at 75–76. The court, therefore, does not take up the broader argument that Plaintiffs seemed to be making in their briefing that blenders do not satisfy the definition of "tobacco product manufacturers" set forth in the TCA's definitions section. *See* Pls.' Mot. at 44–45; Pls.' Reply at 38–39.

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§ 387e(b), and compels registrants to undergo biennial inspections, *id.* § 387e(g), submit a product list, *id.* § 387e(i), and produce reports regarding their products' substantial equivalence to a product marketed as of February 15, 2007, *id.* § 387e(j). Additionally, if an entity is subject to Section 387e's requirements, then it must supply or make available summary health information, including "detailed information regarding data concerning adverse health effects" relating to its tobacco product. *See id.* § 387j(a)(4).

In Plaintiffs' view, subjecting these "mom-and-pop retailers" to the same requirements intended for manufacturers is contrary to the plain text of Section 387e and violates the APA. Additionally, even if the statutory text were ambiguous, they argue, the agency's interpretation is an unreasonable one.[17] Defendants, on the other hand, contend that subjecting pipe tobacco blenders to regulation is compelled by the plain text of the TCA's definition of "tobacco product manufacturer" under 21 U.S.C. § 387(20), and, even if not so compelled, the agency's interpretation is reasonable and warrants deference under *Chevron*. The court concludes that both parties have it wrong.

1. Chevron *Step One*

At the first step of *Chevron*, the court must consider whether Congress has "directly spoken" to the precise question at issue. Here, that question is whether retailers who blend pipe tobacco are, in fact, "engaged in the manufacture, preparation, compounding, or processing of a

[17] Plaintiffs alternatively suggest that the FDA's interpretation is unreasonable because the FDA failed to reasonably explain the impact of the rule on small businesses as required by the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 603–604. *See* Pls.' Mot. at 46. Plaintiffs' RFA claim, *see* Compl., at 30–32, however, has been held in abeyance pending the outcome of the FDA's "new comprehensive plan," *see* Mem. Op., ECF No. 68, at 4 n.3. The court therefore declines to consider the RFA argument.

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tobacco product" and thus subject to the regulatory requirements of 21 U.S.C. § 387e. *See Chevron*, 467 U.S. at 842.

To prevail on their *Chevron* argument at the first step, Plaintiffs must show that the statute unambiguously forecloses the agency's interpretation. *Pharm. Research & Mfrs. of Am. v. FTC*, 790 F.3d 198, 207 (D.C. Cir. 2015). Correspondingly, for the agency to prevail at *Chevron*'s first step, it must show that Congress was not "silent or ambiguous with respect to the specific issue" before the court. *See Humane Soc. of U.S. v. Kempthorne*, 579 F. Supp. 2d 7, 19 (D.D.C. 2008).

As required, the court begins with the statutory text. In pertinent part, 21 U.S.C. § 387e provides that its terms apply to "every person who owns or operates any establishment in any State engaged in the *manufacture, preparation, compounding, or processing* of a tobacco product." *Id.* § 387e(b) (emphasis added). The provision defines the relevant terms as follows:

> 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. § 387e(a)(1) (emphasis added). Application of the foregoing definition is limited to the term's use "[i]n this section." 21 U.S.C. § 387(a).

According to Plaintiffs, a retail pipe tobacco blender is not a "manufacturer"; instead, a retail blender "simply tak[es] two end-use, FDA-approved products and perform[s] a service that consumers themselves could do on their own." Pls.' Mot. at 44. Plaintiffs also contend that because the text of Section 387e distinguishes the manufacturer from "the person who makes final delivery or sale to the ultimate consumer or user," then any retailer who blends pipe tobacco cannot be the person who "manufacture[s], prepar[es], compound[s], or process[es]." *See* Pls.' Reply at 38–39. Thus, Plaintiffs conclude, Section 387e's textual reference to a "person who makes final

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delivery or sale to the ultimate consumer or user" dictates the conclusion that a retailer, typically the entity which makes the final delivery or sale of a tobacco product to the ultimate consumer or user, cannot be subject to the same requirements as a "manufacturer." *See id.*

For its part, the FDA defends its action by pointing to the definition of "tobacco product manufacturer" under 21 U.S.C. § 387(20), which is the TCA's general definitional section. *See* Defs.' Cross-Mot. at 49. As pertinent here, a "tobacco product manufacturer" is defined as "any person, including any repacker or relabeler, who . . . manufactures, fabricates, assembles, processes, or labels a tobacco product[.]" 21 U.S.C. § 387(20). At a minimum, Defendants argue, pipe tobacco blending qualifies as "assembling" or "processing" a tobacco product and therefore blenders are subject to regulation under the Act.

Starting with Plaintiffs' arguments, the court finds them unpersuasive. The court agrees with Defendants that Plaintiffs incorrectly read Section 387e to exclude any and all retailers from its reach. A person's designation as a "retailer" does not preclude application of Section 387e; instead, the focus of the statutory text is on the activity that the person undertakes. If a person in fact "engage[s] in the manufacture, preparation, compounding, or processing of a tobacco product," then he or she is covered by the plain terms of the provision. It matters not, for purposes of Section 387e, whether that establishment is also a retailer. Indeed, crediting Plaintiffs' reading would—as Defendants point out—lead to the absurd conclusion that an establishment could undertake the full manufacture of a tobacco product, but not be subject to Section 387e, as long as it was the entity that made the final sale to the ultimate consumer. The statutory text cannot bear such a result.

At the same time, the court cannot accept the agency's interpretation of Section 387e because its reliance on the general definition of "tobacco product manufacturer" to interpret that

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section is misplaced. Section 387e does not incorporate, as Defendants seem to assert, Section 387(20)'s definition of "tobacco product manufacturer." To the contrary, all of Section 387e's requirements are triggered upon a person "first engaging in the manufacture, preparation, compounding, or processing of a tobacco product," which action compels the person to register with the FDA. 21 U.S.C. § 387e(c); *see id.* §§ 387e(d), (g), (j) (imposing requirements upon persons "required to register under this section"). Thus, the threshold question under Section 387e is whether the blending of pipe tobacco constitutes "the manufacture, preparation, compounding, or processing of tobacco product," not whether a person who engages in blending meets the general definition of "tobacco product manufacturer." To cross-reference a defined term that appears nowhere in Section 387e, as Defendants have done, does not answer that question.

It may be that the act of blending pipe tobacco does constitute the "manufacture, preparation, compounding, or processing of a tobacco product," but the agency neither makes that argument here nor did it make it during the rulemaking process. *Cf.* 81 Fed. Reg. at 29,049 ("All entities that meet the definition of 'tobacco product manufacturer' in [Section 387(20)] of the [TCA], including retail establishments that blend pipe tobacco, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers."). The court cannot now independently analyze that issue. *See State Farm*, 463 U.S. at 43 (stating that the court cannot "substitute its judgment for that of the agency"); *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) ("[I]t is important to remember that if we find that an agency's stated rationale for its decision is erroneous, we cannot sustain its action on some other basis the agency did not mention."). Nor can the court ask the parties for further explanations. *See State Farm*, 463 U.S. at 50 (stating that the court may not accept "*post hoc* rationalizations for agency actions"); *PDK Labs.*, 362 F.3d at 798 (stating that where an agency has not used its experience

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and expertise to bear when interpreting a statute, "it is not for the court 'to choose between competing meanings.'" (quoting *Alarm Indus. Commc'ns Comm. v. FCC*, 131 F.3d 1066, 1072 (D.C. Cir. 1997))). Therefore, the court's review of this issue comes to an end.

2. Chevron *Step Two and Remedy*

Having concluded that the agency's reasoning was misguided, the court quickly disposes of Defendants' contention that the agency's interpretation is entitled to deference at *Chevron*'s second step. When, as here, "an agency incorrectly concludes that Congress mandated a particular regulatory interpretation of a statute—and the agency therefore stops itself at *Chevron* step one—this court will vacate and remand." *Noble Energy, Inc. v. Salazar*, 671 F.3d 1241, 1246 n.5 (D.C. Cir. 2012). As the D.C. Circuit has instructed, "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *PDK Labs.*, 362 F.3d at 798 (citation and internal quotation marks omitted). Here, as discussed, in the final Deeming Rule, the agency wrongly rested its designation of retailers who blend tobacco as subject to Section 387(e)'s requirements solely based on the definition of "tobacco product manufacturer" contained in Section 387(20). Congress compelled no such interpretation. Accordingly, the court vacates application of Section 387e's requirements to retail blenders of pipe tobacco and remands the question to the agency so that it can "bring its experience and expertise to bear in light of competing interests at stake." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (citation omitted).

D. Pipes as "Components or Parts"

At last, the court turns to Plaintiffs' challenge to the FDA's designation of pipes as "components or parts" of a tobacco product subject to regulation under the TCA, as opposed to "accessories" not subject to the Act. Compl. ¶¶ 115–60. The court concludes that the agency's

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designation of pipes as "components," rather than "accessories," is not foreclosed by the statutory text, and defers to the agency's interpretation as the product of "reasoned analysis." *State Farm*, 463 U.S. at 56–57.

As amended by the TCA, the FD&C Act defines a "tobacco product" 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).

21 U.S.C. § 321(rr)(1) (emphasis added). The terms "component," "part," and "accessory" are undefined. In the Deeming Rule, FDA opted to regulate components and parts of the newly deemed tobacco products, but not their accessories. 81 Fed. Reg. at 28,975. The FDA explained that it was not regulating accessories of newly deemed tobacco products "because accessories, unlike components or parts, are expected to have little direct impact on the public health." *Id.*

In making these distinctions, the FDA filled in definitional gaps left by Congress. The agency defined "component or part"[18] as:

> 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) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.

Id. In turn, the agency defined "accessory" to mean:

> any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) [i]s not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition,

[18] The agency acknowledged that "component" and "part" are distinct terms in the TCA, but explained that it would use the terms interchangeably "for purposes of [the] final [Deeming Rule]." 81 Fed. Reg. at 29,042. The FDA reserved the possibility that it would clarify the distinctions between the terms in the future. *Id.*

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> constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Id. at 29,015. The agency concluded in the final Deeming Rule that "[b]oth e-cigarettes and pipes meet" the definition of "components or parts." 81 Fed. Reg. at 29,042. It also provided, by way of contrast, a list of products meeting the definition of "accessories," to include "ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches," as well as "humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product." *Id.* at 28,975.

Plaintiffs challenge the agency's statutory analysis. Relying on a dictionary definition of "component" to mean an "ingredient" or "constituent part," Plaintiffs maintain that "[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 TCA." Pls.' Mot. at 47. Plaintiffs insist that to qualify as a component the object must be "integrated with a product made of tobacco," and, because a pipe is merely a vessel for pipe tobacco, a pipe is simply not a "component." *Id*. at 48. Moreover, even if the statutory term "component" were ambiguous, Plaintiffs say that FDA's classification of pipes as components, rather than unregulated "accessories," is not a reasonable one entitled to deference because there is no record evidence to suggest that pipes do in fact "have . . . direct impact on the public health," rendering the FDA's designation arbitrary and capricious under the APA. *See* 81 Fed. Reg. at 29,102.[19]

[19] To the extent that Plaintiffs alternatively challenge the agency's action as violative of the RFA, *see* Pls.' Mot. at 48–49, a claim currently held in abeyance, *see* Mem. Op., ECF No. 68, at 4 n.3, the court declines to consider this argument.

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1. Chevron *Step One*

The court begins, as always, with the statutory text. *See Sebelius v. Cloer*, 569 U.S. 369, 376 (2013). The TCA does not offer a definition of "component" or "part," so resorting to a dictionary to determine their plain meanings is the best next step. *See Nicopure*, 266 F. Supp. 3d at 383 (citing *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560 (2012)). A "component" is a "constituent part" or "ingredient," *see* Component, Merriam–Webster Dictionary, http://www.merriam-webster.com/dictionary/component, as well as "a constituent element or part," *see* Component, Oxford English Dictionary, 2d ed. (1989). The word "constituent" means an "essential part," "component," or "element." *See* Constituent, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/constituent. And, a "part" is "an essential portion or integral element," *see* Part, Merriam–Webster Dictionary, http://www.merriamwebster.com/dictionary/part, as well as a "piece or section of something which together with another or others makes up the whole (whether actually separate from the rest or not)," *see* Part, Oxford English Dictionary, 3d ed. (2005).

Taking these dictionary definitions together, treating a "pipe" as a "component or part" of a tobacco product is not foreclosed by the statutory text. If "component," in this context, is taken to mean that which is "essential" or critical to the consumption of a tobacco product, then a pipe fits the definition. Neither the pipe nor the pipe tobacco has any independent use or function apart from the other, and Plaintiffs do not assert otherwise. Only when used together do the two create a consumable tobacco product, which is of course the object of regulation under the TCA. None of the definitions of the key terms requires the material regulated to be "integrated" into the tobacco product, as Plaintiffs contend. To the contrary, the word "part" includes in its definition those

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elements used to make up a whole, "whether actually separate from the rest or not." *See* Part, Oxford English Dictionary, 3d ed. (2005).

This is the same conclusion the court reached in *Nicopure*. There, when assessing the agency's decision to regulate empty vaping devices in the Deeming Rule, the court reasoned that the device satisfied the plain meaning of a "component" because, "just as an empty fountain pen is obviously a 'component' of an ink pen . . . even when the ink is sold separately," an empty vaping device is a "component" of an electronic nicotine delivery system. *Nicopure*, 266 F. Supp. 3d at 383–84. That analogy is instructive here: An empty pipe is a "component" of a delivery system for pipe tobacco, even though it is sold separate from the pipe tobacco itself.

To further bolster their argument at *Chevron* step one, Plaintiffs note that the undefined term "component" appears in other provisions of the statute as a bedfellow for terms like "additive" and "ingredient," which Plaintiffs again take to mean that a component must be integrated with a product made of tobacco. Pls.' Mot. at 47 (citing 21 U.S.C. § 387g(a)(3)(B)(ii), 387g(a)(4)(B)(i), 387j(b)(1)(B)). But even if Plaintiffs are right that "additives" and "ingredients" suggest some degree of "integration" into the tobacco product, that reading does not foreclose a pipe from fitting the bill. For instance, as Defendants point out, with respect to cigarettes, the TCA uses the term "component" to include elements segregable from the tobacco itself but necessary to consume the cigarette tobacco, such as filters and paper. *See* 21 U.S.C. § 387g(a)(1)(A). The fact that, as Defendants assert, such components are consumed while smoking, while a pipe is not, is not a limitation on the term "component" found in the statute. Reading any such limitation into the TCA would be at odds with the statute's use of the term "any" to modify "component," 21 U.S.C. § 321(rr)(1), as well as the TCA's clear purpose to provide the FDA the authority and flexibility to effectively regulate the tobacco industry, *see Nicopure*, 266 F. Supp. 3d at 384–85 (citing TCA

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§ 3). Thus, rather than undermining the agency's reading of "component," other uses of the term in the TCA support it.

Accordingly, the court finds that the agency's conclusion that a "pipe" is a "component or part" subject to regulation is not foreclosed by the statutory text and therefore survives *Chevron* step one review. *See Nicopure*, 266 F. Supp. 3d at 384–86 (rejecting the challenger's similar argument that "the context of the TCA as a whole supports [the] argument that the terms 'component or part' must mean a part physically connected to the whole").

2. Chevron *Step Two and Arbitrary and Capricious Review*

Having rejected Plaintiffs' argument at *Chevron*'s first step, the court turns to consider whether the agency's interpretation of the TCA is a permissible one. Assessing Plaintiffs' statutory and APA challenge to FDA's interpretation under the overlapping *Chevron* step two and "arbitrary and capricious" framework, the court holds that the FDA did not act unreasonably in designating "pipes" as "components or parts" subject to regulation.

Plaintiffs argue that, even if the statutory text is ambiguous, the FDA's interpretation is nonetheless an unreasonable one because "[t]here 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," thus compelling the conclusion that a pipe is an "accessory," rather than a "component or part" of a tobacco product. Pls.' Mot. at 48. To that end, Plaintiffs assert that differentiation among pipes is merely for aesthetic reasons, citing public comments to the Proposed Deeming Rule contending that "while [pipes] enable the smoking of tobacco, they present no independent potential harm." *Id.* (citing A.R. 130248).

Plaintiffs' argument is unavailing. For starters, Plaintiffs do not take issue with the definition of "component or part" that the FDA applied to pipes. Plaintiffs do not dispel

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Defendants' argument that pipe design—the size and shape of the bowl, as well as the inclusion of filters—would in fact be "reasonably expected" to alter or affect the "performance," "constituents," and "characteristics" of pipe tobacco. *See* 81 Fed. Reg. at 29,102. Moreover, Plaintiffs also do not explain how pipes are not "to be used with or for the human consumption of a tobacco product." *Id.* at 29,041–42. Thus, the agency's conclusion that a pipe meets the definition of "component or part" is a reasonable one.

Also bolstering the agency's interpretation is a comparison of pipes against objects that qualify as non-regulated "accessories." Observing the agency's provided examples of "accessories," it is clear that pipes are wholly unlike "ashtrays, spittoons, [or] hookah tongs," that do nothing to affect the "performance, composition, constituents, or characteristics of a tobacco product," or "conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product." *Id.* at 28,975. Rather, pipes are "fundamental" to the delivery and consumption of pipe tobacco. *See Nicopure*, 266 F. Supp. 3d at 386. Plaintiffs do not counter that reasoning.

In the alternative, Plaintiffs argue for the first time in their reply brief that the agency's failure to contend with whether to regulate all "components," or not to regulate all "accessories," instead of subsets of each, violates the APA. Plaintiffs did not, however, raise this argument in their initial Motion. *See generally* Pls.' Mot. The court will adhere to the "well-settled prudential doctrine that courts generally will not entertain new arguments first raised in a reply," and therefore declines to consider Plaintiffs' belated challenge. *Aleutian Pribilof Islands Ass'n v. Kempthorne*, 537 F. Supp. 2d 1, 12 n.5 (citing *Herbert v. Nat'l Acad. of Sci.*, 974 F.2d 192, 196 (D.C. Cir. 1992)).

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Accordingly, the court holds that FDA's interpretation of the term "component" to encompass a pipe is not "arbitrary and capricious in substance," *Judulang*, 565 U.S. at 52 n.7, and is the product of "reasoned decisionmaking," *Tripoli Rocketry Ass'n, Inc. v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2006). The FDA's interpretation therefore merits deference.

V. CONCLUSION AND ORDER

For the reasons set forth above, Plaintiffs' Motion for Partial Summary Judgment is granted in part and denied in part, Plaintiffs' Motion for Preliminary Injunction is denied as moot, and Defendants' Cross-Motion for Partial Summary Judgment is granted in part and denied in part, as follows:

1. The Deeming Rule's health warning requirements comport with the TCA and the APA (Count VI) and do not violate the First Amendment (Count VII).

2. The User Fee Rule (Counts II and III) is upheld in its entirety.

3. The process by which the agency designated tobacco retailers who blend pipe tobacco in-store as subject to the requirements of 21 U.S.C. § 387e violates the APA (Count VIII). The court remands this issue to the agency for further proceedings consistent with this Memorandum Opinion.

4. The agency's designation of pipes as "components" of a tobacco product does not violate the APA (Count IX).

No later than June 11, 2018, the parties shall submit a Joint Status Report recommending how to proceed with the remaining, unresolved claims.

Dated: May 15, 2018

Amit P. Mehta
United States District Judge