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.	)	
EN FUEGO TOBACCO SHOP LLC, et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 1:18-cv-01797 (APM)**
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

On April 25, 2014, the U.S. Food and Drug Administration ("FDA") issued a proposed rule announcing its intent to "deem" cigars and certain other tobacco products subject to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"). To "deem" a tobacco product meant that the FDA would subject that product to a host of new regulatory requirements comparable to the statutory and regulatory requirements already imposed under the TCA against cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Among the new proposed requirements

for newly deemed products was a health-warnings labeling regime for packaging and advertisements. With respect to cigar products, the proposed rule put forward two alternatives. Under "Option 1," the FDA would make all categories of cigar products subject to the TCA; under "Option 2," the FDA would regulate "only a subset of cigars," excluding "premium cigars" from the scope of the Rule. Generally speaking, "premium cigars" are hand-rolled, made with a higher-grade tobacco, and are more expensive. FDA's selection of Option 2 would mean that premium cigars would be excluded from the warnings label requirement.

Industry groups representing premium cigar retailers and manufacturers submitted comments expressing concerns about the proposed rule. These commenters objected to the regulation of premium cigars and asserted, among other things, that premium cigars do not pose the same public health concerns as mass-market cigars and other tobacco products because premium cigar consumers are only occasional users of the product and use the product differently. The public health effects of this difference in use, the commenters argued, are borne out by studies showing that premium cigar users have far lower disease and mortality rates than consumers of cigarettes and other tobacco products. And because of these differences in use, the commenters maintained, the same health warnings regime proposed for mass-market cigars and other tobacco products was not warranted for premium cigars.

The FDA rejected these arguments, concluding in its final rule that no evidence put forward during the notice-and-comment period supported exempting premium cigars from regulation. Accordingly, the FDA's final rule, known as the "Deeming Rule," selected Option 1: "deeming" all cigars, including premium cigars, to be subject to the TCA, and imposing health warnings requirements on all cigar products.

Plaintiffs in this case—a premium cigar retailer, a premium cigar manufacturer, and a non-profit association that represents premium cigar retailers and manufacturers—brought this action in January 2018 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's warnings label regime for premium cigars on three primary bases: (1) the warnings label regime infringes on Plaintiffs' First Amendment rights; (2) the FDA imposed the new warnings label regime in violation of the Administrative Procedure Act ("APA"); and (3) the promulgation of the Deeming Rule violated the Appointments Clause.

For the reasons set forth below, the court finds that the FDA's subjecting of premium cigars to warnings requirements to be arbitrary and capricious in violation of the APA, insofar as the agency failed to provide a reasoned explanation for this action. The court thus declares unlawful and vacates that portion of the Deeming Rule that mandates premium cigars display designated public health warnings on packaging and advertisements. The court does not reach Plaintiffs' First Amendment and Appointments Clause challenges.

II. BACKGROUND

A. Statutory and Regulatory Background

The court starts with a brief overview of the relevant statutory and regulatory backdrop for this case.

In 2009, Congress enacted the TCA to empower the FDA to regulate and set national standards regarding the manufacturing, marketing, and distribution of tobacco products. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009). Congress acknowledged the "inherent[] dangerous[ness]" of tobacco products and nicotine and the strong public interest in regulating tobacco products and their advertising and

promotion. *Id.* § 2. Congress also expressed its interest in reducing youth tobacco use, particularly in light of judicial findings that major U.S. tobacco companies specifically targeted and marketed their products to youth. *Id.* § 2(15). Congress further recognized that no other federal agency except the FDA "possesses the scientific expertise needed to implement effectively all provisions of the [TCA]." *Id.* § 2(45).

In light of these findings, the TCA authorized the Secretary of HHS to regulate the manufacture, distribution, and marketing of tobacco products. *Id.* § 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. 21 U.S.C. § 387a(b). It also reserved future application of the TCA to "any other tobacco products that the Secretary [of HHS] by regulation *deems* to be subject to this chapter." *Id.* (emphasis added). Congress defined "tobacco product" to mean "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)." *Id.* § 321(rr)(1).

B. Regulatory Background

1. The Proposed Deeming Rule

In the years following Congress's enactment of the TCA, cigar products were largely free from FDA regulation because cigars were not expressly listed in the Act's definition of "tobacco product." That unregulated status would soon change. 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; Regulations 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"). As a "deemed" product, cigars would become subject to a host of regulatory requirements comparable to those imposed on cigarettes and other tobacco products.

The FDA did not, however, immediately announce an intention to deem *all* cigar products. Rather, in the Proposed Deeming Rule, the FDA offered "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 types of cigars meeting the statutory definition of "tobacco product"—including premium cigars—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, FDA suggested the following definition for "covered cigar":

> [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 eight identified characteristics contained in the definition of "covered cigar" were included as a way to exclude premium cigars from regulation. 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 "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 also sought comment on the "relative merits of Option 1 versus Option 2." *Id.* at 23,145. In so doing, it aimed "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." *Id.* at 23,143. Though the FDA maintained that "all cigars are harmful and potentially addictive," it noted that "it has been suggested that different kinds of cigars 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 23,143. To that end, the FDA sought comments that "tak[e] 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 23,145.

2. Comments on the Proposed Deeming Rule

Numerous members of the public submitted comments on the Proposed Deeming Rule. Among them was Cigar Rights of America ("CRA"), a non-profit association that represents consumers and manufacturers of premium cigars.[1] *See* Joint Appendix Vol. 3, ECF No. 81-2 [hereinafter J.A. Vol. 3], at 304.[2] CRA advocated for Option 2, arguing that premium cigars should be exempted from FDA regulation and from the warnings regime described in the Proposed Deeming Rule. *See id.* at 304–38. According to CRA, the premium cigar consumer is "different from the typical tobacco consumer," and therefore the same concerns attendant to cigarette and other tobacco product use—namely youth initiation and nicotine addiction—are not present with

[1] Though not a plaintiff in this case, CRA is a plaintiff in the related case, *Cigar Association of America et al. v. FDA et al.*, 16-cv-1460.
[2] Unless otherwise noted, all ECF citations reference the docket in *Cigar Association*, 16-cv-1460.

premium cigar use. *Id.* at 307. CRA cited a number of studies supporting its claims and concluded that "the proposed warnings lack a sound evidentiary basis." *Id.* at 322.

Other cigar retailers and manufacturers, as well as advocacy groups representing premium cigar consumers, echoed CRA's arguments in their own comments on the Proposed Deeming Rule. Because "premium cigar consumers are much older than other tobacco consumers," one commenter opined, "there is simply no basis for any conclusion that regulating premium cigars will meaningfully impact youth access to, or use of, tobacco products." *Id.* at 254 (comment from Holt's Cigar Holdings, Inc.). Others contested the statistics regarding youth use cited in the Proposed Deeming Rule and cited contrary studies showing that underage premium cigar use is minimal, thereby warranting "a more measured degree of regulation." *Id.* at 350 (comment from International Premium Cigar & Pipe Retailers Association ("IPCPR")). Commenters also pointed out that "usage data show that premium cigars products are consumed infrequently," at a "much lower rate" than other tobacco products, and are consumed "often in a celebratory nature, by adults." *Id.* at 348 (same). In light of these usage patterns, commenters insisted, "FDA's final regulations should not take a one-size-fits-all approach to the regulation of a diverse suite of tobacco products, and should instead impose regulatory requirements for premium cigars consistent with recognized public health differences." *Id.* at 349 (same).

3. The Final Deeming Rule

On May 10, 2016, the FDA promulgated the final Deeming Rule. It adopted Option 1, deeming all categories of cigars, including premium cigars, to be subject to the TCA. *See* 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").

The Deeming Rule sets out, among other things, comprehensive warnings requirements for cigar product packaging and advertisements. All cigar product packages must display one of the following six health warnings 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.

21 C.F.R. § 1143.5(a)(1). These health warnings must be displayed on a rotating basis. *See id.* § 1143.5(c). On cigar packages, each of the six health warnings statements "must be randomly displayed in each 12-month period, in as equal a 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 warnings 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

[3] This warning statement can be replaced with an 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).

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 warnings statement must be posted at the retailer's point-of-sale on an 8.5x11-inch "clear, legible, and conspicuous" sign. *Id.* § 1143.5(a)(3). As to print and other visual advertisements, the warnings 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)(2). FDA announced May 10, 2018, as the effective date of the warnings label requirement. *Id.* § 1143.13.

The final Deeming Rule addressed those comments that advocated for excluding premium cigars from the Rule's requirements. The FDA stated that it "concluded that deeming all cigars, rather than a subset, more completely protects the public health." 81 Fed. Reg. at 29,020. 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.* Though the FDA admitted that most of the studies it relied on "do not explicitly pertain to premium cigars," it concluded that, because premium cigars "share the same characteristics" as traditional, large cigars "and are generally smoked in similar ways," studies about the health effects of smoking traditional, large cigars are equally applicable to premium cigars. *Id.*

The FDA dismissed commenters' contentions that different patterns of use for premium cigar users support exempting the product from regulation altogether. "The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale," the FDA stated, "does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others." *Id.* According to the FDA, even though commenters cited studies indicating that some cigar smokers may absorb less tobacco smoke through cigars, those same studies "also show that all cigar smoking is harmful." *Id.* at 29,024. The agency concluded that "all cigars are potentially addictive" and "cigar use of all types can lead to negative health effects." *Id.* at 29,022; *see also id.* at 29,024.

Specifically in response to commenters' argument that the proposed warning labels for premium cigars "lack a sound scientific basis" because of different consumption rates, inhalation patterns, and demographics of premium cigar users, the FDA merely remarked that it "finds there is a strong scientific basis to require health warnings on cigar packages and in cigar advertisements (as well as on signs for unpackaged cigars), which was extensively discussed in the [Proposed Deeming Rule]." *Id.* at 29,062 (citing 79 FR 23,142 at 23,167 through 23,170).

4. The Premium Cigar Rulemaking

Just over a year later, the FDA re-opened the door it seemed to have shut on proponents of not regulating premium cigars. In July 2017, the FDA announced a new comprehensive plan for tobacco regulation. Press Release, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death,* at 1 (July 27, 2017) (hereinafter "July 2017 Press Release").[4] As part of that announcement, the FDA said it intended to issue an advanced notice of proposed rulemaking ("ANPRM") seeking additional information concerning how "premium"

[4] Available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

cigars might be defined and how the patterns of use may impact public health. *Id.* At the same time, the Agency delayed many of the compliance deadlines of the Deeming Rule's premarket approval and substantial equivalence requirements, but it did not stay imposition of the health warnings requirements. *Id.*

The FDA issued the ANPRM regarding premium cigars the following year. The FDA's new premium cigar rulemaking sought "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). The agency observed that while it had received comments in response to the Proposed Deeming Rule claiming that the health risks associated with the use of premium cigars were not significant because of the patterns of premium cigar use, these comments ultimately failed to provide an adequate scientific basis for excluding those products from regulation. *Id.* Thus, the FDA invited submission of "new and different" comments, data, research results, and other information, *id.*, related to three topics: (1) the "definition of premium cigars"; (2) usage patterns of premium cigars; and (3) "[p]ublic health considerations associated with premium cigars," *id.* at 12,903. The FDA also asked the public to submit studies or information regarding the Deeming Rule's current health warnings mandates and requested comment on "whether any additional or alternative warning statements would be appropriate." *Id.* at 12,904. The rulemaking remains ongoing.

B. The *Cigar Association* Litigation

On July 15, 2016, a group of plaintiffs, led by the Cigar Association of America, filed suit in this District against the FDA, HHS, and others. *See* Compl., *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460 (D.D.C.), ECF No. 1. Plaintiffs in *Cigar Association* are three non-profit

associations that represent cigar manufacturers, importers, distributors, suppliers, and consumers, as well as premium cigar and tobacco retail shops (collectively "*Cigar Association* Plaintiffs"). *Id*. ¶¶ 9–11. The *Cigar Association* Plaintiffs' nine-count complaint challenged the Deeming Rule as well as a separate rule[5] on a number of grounds. As relevant here, the *Cigar Association* Plaintiffs alleged that (1) the FDA's decision not to select Option 2, i.e., excluding premium cigars from the Deeming Rule, is unlawful under the APA (Count V); and (2) the warning label requirements for all cigar products contravene the APA (Count VI) and the First Amendment (Count VII). *Id.* ¶¶ 82–160. Notably, although the *Cigar Association* Plaintiffs challenged the deeming of premium cigars, they did not assert the narrower claim that, even if deemed for other regulatory purposes like pre-market approval, the warnings label requirement as applied to premium cigars was unlawful. *See generally id.*

After the Plaintiffs filed their opening brief for summary judgment, the FDA announced, as discussed above, its intention to issue an ANPRM concerning premium cigars. *See* July 2017 Press Release; *see also Cigar Ass'n*, 315 F. Supp. 3d 143, 156–57 (D.D.C. 2018). Partly in response to that intended rulemaking, the Plaintiffs thereafter opted to defer litigating their premium cigar-specific claim, i.e., the claim that the agency's selection of Option 1 over Option 2 was an arbitrary and capricious agency action. *See* Joint Report Regarding Briefing Schedule, ECF No. 53; *Cigar Ass'n*, 315 F. Supp. 3d at 157–58. Briefing proceeded on Plaintiffs' other claims, including the claims asserting that the warnings regime as to *all cigars* violated the First Amendment and the APA. *See* ECF Nos. 120, 124, 125, 128, 129, 132.

[5] The other rule, also promulgated in May 2016, but not at issue here, is known as the "User Fee Rule." *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. That Rule assesses "user fees" on manufacturers and importers of cigars and pipe tobacco, but not other newly deemed products, like e-cigarettes. *See* 81 Fed. Reg. at 28,711–12.

On May 15, 2018, the court granted in part and denied in part the *Cigar Association* Plaintiffs' cross-motions for partial summary judgment. *See Cigar Ass'n*, 315 F. Supp. 3d at 189. As relevant here, the court ruled that the health warnings requirement was lawful as to all cigar products under both the First Amendment and the APA. *See id.* at 159–75. Specifically, as to the First Amendment claim, applying the test set forth in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), the court held that the health warnings requirement was reasonably related to a substantial government interest and not unduly burdensome. *See Cigar Ass'n*, 315 F. Supp. 3d at 163–74. The court also held that the decision to impose warnings as to all cigars was not arbitrary and capricious. *See id.* at 159–63. Finally, because the *Cigar Association* plaintiffs had opted to defer litigating the Option 1 versus Option 2 issue, the court did not address the question whether the agency's recent announcement that it was seeking additional information about regulating premium cigars rendered the FDA's decision to regulate premium cigars arbitrary and capricious. *Id.* at 175–77.

Thereafter, to enable an immediate appeal, the court entered judgment in favor of Defendants as to those claims challenging the warnings requirement. The court, however, enjoined enforcement of the warnings regime pending the outcome of appeal. *See Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 317 F. Supp. 3d 555, 563–64 (D.D.C. 2018). The *Cigar Association* matter remains under review before the D.C. Circuit. *See Cigar Ass'n of Am. v. FDA*, 18-5195 (D.C. Cir.).

C. The *En Fuego* Litigation

Plaintiffs in the instant case are three entities: (1) En Fuego Tobacco Shop LLC, "a premium cigar retailer and lounge with locations" around Texas; (2) Cuba Libre Enterprises LLC (doing business as El Cubano Cigars), "a manufacturer of handmade premium cigars" based in

Texas; and (3) the Texas Cigar Merchants Association, "a Texas-incorporated not-for-profit association representing premium cigar manufacturers and retailers in the State of Texas." Am. Compl., Case No. 18-cv-1797, ECF No. 20 [hereinafter Am. Compl.], ¶¶ 20–22 (collectively, "Plaintiffs"). These Plaintiffs originally brought this action in January 2018 in the District Court for the Eastern District of Texas against the FDA and its Commissioner, and HHS and its Secretary, challenging the Deeming Rule on various grounds as it applies only to premium cigars. *See generally* Compl., ECF No. 1; *see also* Am. Compl. The court in Texas transferred the case here based on the Fifth Circuit's "first-to-file rule" in March 2018, *see* Mot. to Transfer, ECF No. 18, and after some litigation on the transfer, this court consolidated the *En Fuego* case with the *Cigar Association* litigation, *see* Mem. Op. and Order of January 11, 2019, Case No. 18-cv-1797, ECF No. 78.

The *En Fuego* Plaintiffs' Amended Complaint contains eight counts. Taken together, those counts challenge (1) the Deeming Rule's health warnings mandate as its relates to premium cigars under the First Amendment (Counts I–III), the TCA (Count V), and the APA (Count VI); (2) the Deeming Rule's warnings plan pre-approval requirement under the First Amendment (Count IV); and (3) the manner of the Deeming Rule's promulgation under the Appointments Clause (Counts VII and VIII). Am. Compl. ¶¶ 64–149. Plaintiffs moved for summary judgment and a permanent injunction, *see* Pls.' Mot. for Summ. J. , ECF No. 120 (hereinafter "Pls.' Mot."), and Defendants filed a cross-motion for summary judgment, *see* Defs.' Cross Mot. for Summ. J., ECF. No. 124 (hereinafter "Defs.' Mot."). These motions are now ripe for review.

III. LEGAL STANDARD

When reviewing 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 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)). The district court "sits as an appellate tribunal," reviewing the entire case as a question of law. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (collecting cases). Accordingly, the court need not engage in lengthy factfinding and as a general rule, judicial review is limited to the administrative record. "It is black-letter administrative law that in an [Administrative Procedure Act] case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) (internal quotation marks omitted; alteration in original); *see also* 5 U.S.C. § 706 ("[T]he court shall review the whole record or those parts of it cited by a party . . . .").

The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "This is a 'narrow' standard of review as courts defer to the agency's expertise." *Ctr. for Food Safety v. Salazar*, 898 F. Supp. 2d 130, 138 (D.D.C. 2012) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The court's review, however, is not toothless. The court must satisfy itself that the agency has "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." *State Farm*, 463 U.S. at 43 (internal quotation marks omitted). When an agency "has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (quoting *BellSouth Corp. v. FCC*,

162 F.3d 1215, 1222 (D.C. Cir. 1999)). "Moreover, an agency cannot fail to consider an important aspect of the problem or offer an explanation for its decision that runs counter to the evidence before it." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015) (cleaned up). If the issuing agency has "failed to address significant comments raised during the rulemaking," the regulation will be deemed arbitrary and capricious. *Ass'n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 441 (D.C. Cir. 2012); *see also Select Specialty Hosp.-Bloomington, Inc. v. Burwell*, 757 F.3d 308, 312 (D.C. Cir. 2014) (noting that when "an agency's failure to state its reasoning or to adopt an intelligible decisional standard is [ ] glaring[,] [ ] we can declare with confidence that the agency action was arbitrary and capricious" (quoting *Checkosky v. SEC*, 23 F.3d 452, 463 (D.C. Cir. 1994)). After-the-fact rationalizations "advanced to remedy inadequacies in the agency's record" or in the agency's explanation will not suffice. *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1165 (D.C. Cir. 1987).

IV. DISCUSSION

A. Claim Preclusion

Before turning to the merits of Plaintiffs' claims, the court starts with a threshold issue: claim preclusion.[6] Defendants argue the court's ruling in *Cigar Association* bars the *En Fuego* Plaintiffs' claims. Defs.' Mot. at 11. Under the doctrine of claim preclusion, "a final, valid judgment on the merits precludes any further litigation between the same parties on the same cause of action." *Stanton v. D.C. Court of Appeals*, 127 F.3d 72, 78 (D.C. Cir. 1997). To determine when claim preclusion applies, courts look to see if the suit's prior litigation "(1) involv[ed] the same claims or cause of action, (2) between the same parties or their privies, and (3) there has been

[6] Although Defendants frame this threshold issue in terms of "res judicata," Defs.' Mot. at 11, that label is inexact, as res judicata includes two preclusive doctrines—claim preclusion and issue preclusion. *See Taylor v. Strugell*, 553 U.S. 880, 892 (2008). Because Defendants only assert claim preclusion, the court refers only to that term and eschews the term res judicata.

a final, valid judgment on the merits, (4) by a court of competent jurisdiction." *Smalls v. United States*, 471 F.3d 186, 192 (D.C. Cir. 2006). In this case, Defendants assert that the first claim preclusion prong is satisfied because, "[a]t their core, both [*Cigar Association* and *En Fuego*] involve constitutional and administrative law challenges to the FDA's decision to require cigar products to carry health warnings." Defs.' Mot. at 12. As to the second prong, Defendants argue that the *En Fuego* Plaintiffs are in privity with two of the *Cigar Association* Plaintiffs, the International Premium Cigar and Pipe Retailers Association ("IPCPR") and Cigar Rights of America ("CRA"). Defendants emphasize that *En Fuego* Plaintiff Texas Cigar Merchants Association is the official state association of *Cigar Association* Plaintiff IPCPR, and that Plaintiffs En Fuego and El Cubano Cigars in this case were members of IPCPR when the *Cigar Association* action was "filed, briefed, and argued." *Id.* at 13. These relationships satisfy the privity requirement, Defendants say. Finally, for the third prong, Defendants point out that a final judgement was entered in *Cigar Association* on Counts VI and VII. Relatedly, Defendants contend that the rule against claim splitting, which "requires that all claims arising out of a single wrong be presented in one action," forecloses the *En Fuego* Plaintiffs' claims. *Id.* at 14 (quoting *Dorsey v. Jacobson Holman PLLC*, 764 F. Supp. 2d 209, 212 (D.D.C. 2011)).

Defendants' claim preclusion defense founders on the second prong: they have not established privity between the *En Fuego* Plaintiffs and the *Cigar Association* Plaintiffs based on the former's membership in the latter. Although the D.C. Circuit appears not to have grappled with this issue, commentators have warned that "great care should be taken before binding all members to an association loss." 18A Charles Alan Wright et al., *Federal Practice & Procedure* § 4456 (2d ed. 2017). An association "may choose to conduct a particular suit with an eye to its interests in other suits and other questions," making it unfair to bind a member to the association's

litigation result. *Id.* Mindful of this concern, some commentators and courts have distinguished between a member who "actively participates" in the association's litigation and one who does not. "Any member who actively participated in the first action should [ ] be barred, without insisting on the same degree of involvement that is required by ordinary standards of participation and control. Other members, however, should not be precluded . . . ." *Id.* (footnote omitted); *see also Cal. Cosmetology Coal. v. Riley*, 871 F. Supp. 1263, 1267 (C.D. Cal. 1994) ("Under federal law, mere membership in a trade association alone does not create the privity necessary to bind the member to a judgment against an organization."), *aff'd* 110 F.3d 1454 (9th Cir. 1997). The court adopts that approach here. Defendants bear the burden of establishing claim preclusion, *see Taylor v. Sturgell*, 553 U.S. 880, 907 (2008), but have offered no evidence of litigation-related activity by any *En Fuego* Plaintiff in the *Cigar Association* matter. Their mere membership in or affiliation with the *Cigar Association* Plaintiffs IPCPR and CRA therefore does not foreclose their present claims.

Citing the Supreme Court's decision in *Taylor*, Defendants argue that "[e]ven if Plaintiffs were not members or affiliates of those associations, their claims would still be barred, because in *Cigar Association* they were 'adequately represented by someone with the same interests who [was] a party,'" and a "party bound by a judgment may not avoid its preclusive force by relitigating through a proxy." Defs.' Reply in Further Supp. of Defs.' Mot., ECF No. 132, at 5 (quoting *Taylor*, 553 U.S. at 894–95) (internal quotation marks and citation omitted). But neither of these circumstances apply here. The Supreme Court has found that a nonparty's claims are precluded based on adequate representation in a prior action "only if, at a minimum: (1) The interests of the nonparty and her representative are aligned; and (2) either the party understood herself to be acting in a representative capacity or the original court took care to protect the interests of the nonparty."

Taylor, 553 U.S. at 900 (citation omitted). This exception to the general rule against nonparty claim preclusion applies "in certain limited circumstances," such as class actions and suits brought by trustees, guardians, and other fiduciaries. *Id.* at 894 (internal quotation marks and citation omitted). Here, Defendants point to nothing other than IPCPR's and CRA's status as associations to establish that they were acting in a representative capacity for certain *En Fuego* Plaintiffs. As discussed above, the *En Fuego* Plaintiffs' mere membership or affiliation with the *Cigar Association* Plaintiffs is not enough to come within the "limited circumstances" of the adequate-representation exception. Nor have Defendants established that the *En Fuego* Plaintiffs are "proxies" for IPCPR and CRA. That exception requires a showing that the person that did not participate in the earlier litigation is "the designated representative of a person who was a party to the prior adjudication." *Id.* at 895. Defendants have come forward with no evidence to establish such relationship between the *En Fuego* Plaintiffs and the *Cigar Association* Plaintiffs. Defendants' claim preclusion defense thus fails.

B. Challenge to the Health Warnings Requirement

The court now turns to the merits. Plaintiffs challenge the Deeming Rule's health warnings requirement for premium cigar packaging and advertisements on three primary grounds. First, Plaintiffs argue that the warnings label regime, including the mandated agency preapproval of a label-rotation plan, as applied to premium cigars violates the First Amendment. Pls.' Mot. at 14–33. Second, Plaintiffs contend that the FDA's adoption of the warnings requirement for premium cigars was not the product of reasoned decisionmaking and thus is arbitrary and capricious and violates the APA. *Id.* at 33–42. Third, Plaintiffs indirectly challenge the warnings mandate by asserting that the Deeming Rule, in its entirety, was unconstitutionally issued by the FDA's Associate Commissioner for Policy in violation of the Appointments Clause. *Id.* at 42–44.

Because the court agrees with Plaintiffs that the FDA's rulemaking was not the product of reasoned decisionmaking and therefore violates the APA, the court does not reach Plaintiffs' First Amendment and Appointments Clause arguments. *See Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 197 (2009) ("Our usual practice is to avoid the unnecessary resolution of constitutional questions."); *see also Qassim v. Trump*, 927 F.3d 522, 530 (D.C. Cir. 2019) (stating that "*courts must* 'avoid the premature adjudication of constitutional questions' and 'not . . . pass on questions of constitutionality . . . unless such adjudication is unavoidable'" (emphasis added) (quoting *Matal v. Tam*, 137 S. Ct. 1744, 1755 (2017))).[7] In light of this ruling, the court also need not reach the First Amendment challenge to the warnings plan preapproval requirement, as the court invalidates the warnings requirement for premium cigars.

1. Reasoned Decisionmaking

"One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2018). An agency therefore "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). Although an agency "need not address every comment" made during the notice and comment period, "it must respond in a reasoned manner to those that raise significant problems." *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003) (quoting *Reytblatt v. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997)). And while the

[7] Because the court finds that the health warnings requirement was not the product of reasoned decisionmaking, the court need not address Plaintiffs' other APA claims that (1) the FDA's enforcement of the warnings regime on premium cigars is arbitrary and capricious in light of the recently opened, ongoing rulemaking regarding of premium cigars, Defs.' Mot. at 33–34, and (2) the FDA neglected to make statutorily required findings that imposing health warnings on premium cigars would reduce tobacco use, *id.* at 40–42.

agency action under review is "entitled to a presumption of regularity[,] . . . that presumption is not to shield [an] action from a thorough, probing, in-depth review." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977). "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action." *County of Los Angeles*, 192 F.3d at 1021 (internal quotation marks and citation omitted).

Plaintiffs maintain that the FDA's extension of warning labels to premium cigars was insufficiently explained in light of comments arguing that the labels are "particularly ill-suited" to premium cigars. Pls.' Mot. at 38; Pls.' Reply in Further Supp. of Pls.' Mot. and Opp'n to Defs.' Mot., ECF No. 128 [hereinafter Pls.' Reply], at 28. As the court sees it, Plaintiffs' argument is essentially two-fold. First, the agency failed to supply a reasoned explanation to substantiate applying health warnings to premium cigar products because the warnings themselves are factually unfounded for such products. Second, the agency did not adequately justify the need for health warnings for premium cigars because premium cigar consumers already appreciate the risks of regular use. In support of both arguments, commenters to the Proposed Rule presented evidence supporting that premium cigars have different usage patterns than other cigar and tobacco products, they are almost never used by youth, and they are instead used by older, higher income, and better educated consumers. *See, e.g.*, J.A. Vol. 3 at 307, 310 (CRA comment citing evidence indicating that the premium cigar consumer is "different from the typical tobacco consumer," including studies showing that premium cigar users tend to be far older than users of other tobacco products, and studies showing that youth overwhelmingly prefer machine-made or filtered cigars over premium cigars). In Plaintiffs' view, these demographic differences and usage patterns establish that (1) premium cigars present insufficient public health concerns and thus render the

warnings inaccurate as to premium cigars, and (2) consumers would not benefit from warnings because they already use the product "in a manner showing [] consumers understand the risks of excessive use," Pls.' Mot. at 28; *see also* Pls.' Reply at 15. The FDA grappled with the first of these arguments but not the second.

The Final Deeming Rule rejected commenters' arguments that the patterns of use and demographic data for premium cigars support exempting the product from regulation. "The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale," the FDA explained, "does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others." 81 Fed. Reg. at 29,020. Though commenters had cited studies indicating, for example, that some cigar smokers may absorb less tobacco smoke through cigars, the agency determined that those same studies "also show that all cigar smoking is harmful." *Id.* at 29,024. The FDA concluded that "all cigars are potentially addictive," and "cigar use of all types can lead to negative health effects." *Id*. at 29,022. Because "[a]ll cigars produce toxic cigar smoke" and "[a]ny cigar use exposes the mouth and throat to tobacco smoke," health risks still exist regardless of how often consumers use premium cigars. *Id*. at 29,024–05. Elsewhere, the agency addressed concerns from commenters that "questioned whether large cigars, particularly premium cigars, should be required to carry an addiction warning because users do not inhale the cigar smoke." *Id.* at 29,069. The agency answered: "Regardless of whether cigar smokers inhale, they are still subject to the addictive effects through nicotine absorption . . . . Therefore, consumers using premium and other cigars can become addicted to cigars given the absorption of nicotine." *Id.* Such responses demonstrate that the agency understood the doubts expressed about the warnings' accuracy with respect to premium cigars and addressed those concerns in a reasoned manner.

The same cannot be said, however, of the agency's response to commenters' assertions that, in light of usage patterns and user demographics, warnings are unnecessary to inform premium cigar users about health risks. Critical to understanding the court's different conclusion is the manner in which FDA framed the issue of regulating cigar products. At the outset, the Proposed Deeming Rule submitted that differences between premium cigars and other types of cigars might warrant a different approach with respect to each category of product. "[I]t has been suggested that different kinds of cigars may have the potential for varying effects on public health," the agency wrote, "based on possible differences in their effects on dual use, youth initiation and frequency of use by youth and young adults." 79 Fed. Reg. at 23,143. "Accordingly," the agency said, it "is seeking comment on these options to determine whether all cigars should be subject to deeming and *what provisions of the proposed ruled may be appropriate or not appropriate for different kinds of cigars.*" *Id.* (emphasis added). Thus, the agency sought comment not only on the global question of whether or not to deem premium cigars but also whether particular types of regulation were appropriate for premium cigars. Once the FDA structured the Proposed Deeming Rule in this way, it became incumbent on the agency to address, if challenged, the propriety of subjecting a defined category of cigar product to a particular form of regulation, "articulat[ing] with reasonable clarity its reasons for decision, and identify[ing] the significance of the crucial facts." *Greater Bos. Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970). For purposes of this case then, the FDA had to explain not only why it deemed premium cigars but also why health warnings for premium cigar packaging and advertising are appropriate. *See* Pls.' Reply at 27. The agency failed to do so.

In response to comments questioning the need for warning labels for premium cigars, the agency in the final Deeming Rule responded as follows: "FDA finds there is a strong scientific

basis to require health warnings on [premium] cigar packages and in cigar advertisements (as well as on signs for unpackaged cigars), which was extensively discussed in the [Proposed Deeming Rule]." 81 Fed. Reg. at 29,062 (citing 79 Fed. Reg. 23142 at 23,167–70). The circularity of this response is evident. Rather than analyzing the behavior of premium cigar consumers, consumer understanding of the risks associated with premium cigar products, or potential gaps in consumer knowledge that warnings might address, the FDA directed readers to the Proposed Deeming Rule. But the Proposed Deeming Rule itself makes clear that the agency was actively contemplating whether health warnings should be required for premium cigars at all. *See* 79 Fed. Reg. at 23,150. "[A]lthough all cigars are harmful and potentially addictive," the Proposed Deeming Rule explains:

> [I]t has been suggested that different kinds of cigars (e.g., small cigars, cigarillos, large cigars, premium cigars) may have the potential for varying effects on public health, if there are differences in their effects on youth initiation, the frequency of their use by youth and young adults, and other factors. In addition, the proportion of cigar smokers showing clear signs of dependence remains unknown, and usage patterns indicate that cigar only use beginning in adulthood is less likely to produce addiction than the use of cigarettes.

Id. Accordingly, the Proposed Deeming Rule sought "comment on whether all cigars should be subject to deeming and what additional restriction(s) may or may not be appropriate for different kinds of cigars." *Id.* The FDA's citation back to the Proposed Deeming Rule therefore leads right back to the original question whether warning labels are necessary for premium cigars. This obviously will not do for reasoned decisionmaking.

This finding is underscored by an inspection of the actual pages of the Proposed Deeming Rule on which the FDA relied in the final Deeming Rule when explaining the rationale for warning labels for premium cigars. As noted, the agency answered commenters by saying that there "is

strong scientific basis to require health warnings on cigar packages and in cigar advertisements," and it cited back to the Proposed Deeming Rule at "79 FR 23142 at 23167 through 23170" in support. 81 Fed. Reg. at 29,062. But that portion of the Proposed Deeming Rule says little about users' misconceptions or knowledge gaps about the health risks of premium cigar products. Instead, these pages primarily discuss the scientific studies supporting the accuracy of each of the proposed warnings, with almost no discussion of the necessity for these warnings for premium cigars. The FDA does not, for example, explain on those pages why informational concerns generally attendant to cigar or other tobacco consumption obtain with respect to premium cigars. Nor does this portion of the Deeming Rule cite any study indicating a lack of information about the health consequences of premium cigar use on the part of the public in general or premium cigar users in particular.

The most that can be said about this portion of the Proposed Deeming Rule is that it relies upon evidence to justify the warnings regime that does not apply to premium cigars and their users. The FDA touted the importance of warning labels to: (1) "help consumers better understand and appreciate the risks and characteristics of tobacco products"; and (2) "help correct current misperceptions about newly deemed products." Hr'g Tr., ECF No. 151, at 61; *see also* 79 Fed. Reg. at 23,163 ("FDA believes it is critical to include a warning on all such [tobacco] products to help consumers better understand and appreciate the addictive nature of these products."). The FDA was particularly focused on youth misimpressions about the health risks of cigar and tobacco products. *See* 79 Fed. Reg. at 23,146. The various studies the agency cited to support these objectives do not, however, implicate such concerns with respect to premium cigars.

For example, in support of the proposition that "youth perceive cigars in a more positive light than cigarettes and believe they are less harmful," the Proposed Deeming Rule offers two

different studies. *See* 79 Fed. Reg. at 23,169. The first study, by the Office of the Inspector General, involved a self-administered survey of 230 teenagers as well as various focus groups that included a mix of teenage cigar users and teenage non-users. *See* Office of Inspector General, *Youth Use of Cigars: Patterns of Use and Perceptions of Risk*, OEI-06-98-00030 (1999). While some teens who participated in the focus groups reported anecdotally that they had smoked traditional, large cigars, and even one teenager reported purchasing an expensive cigar at one point, the study did not differentiate overall between the types of cigars teenagers used, or which perceptions about the harmfulness of cigars were held by which groups of teenagers—those who used large, traditional cigars; those who used small cigars or cigarillos; or non-smoking teenagers. *Id.* The second study, also a survey, suffers from the same flaw. It noted that the study subsumed multiple types of cigars under the term "cigar," and thus it did not differentiate between types of cigars used by the participants, nor did it indicate which beliefs were held by students who smoke and students who do not smoke. R. Malone, V. Yerger, & C. Pearson, *Cigar Risk Perception in Focus Groups of Urban African American Youth*, 13 J. of Substance Abuse 549 (2001). The study thus offers no insight into youth perceptions of premium cigars.

Other studies cited within these pages of the Proposed Deeming Rule do not help the FDA's cause. For instance, in support of the finding that "some cigar smokers believe that cigars are a safe alternative to cigarettes," *see* 79 Fed. Reg. at 23,169, the Proposed Rule cites a cross-sectional health risk survey that divided participants into non-users, cigarette-only users, cigar-only users, and dual users. But the cigar-only user category included not only users of large cigars, but also cigarillos and little cigars. *See* A. Brooks et al., *Cigars, Cigarettes, and Adolescents*, 32 Am. J. of Health Behavior 640, 642 (2008). Yet another study, cited to support the contention that cigar smokers exhibit an "optimistic bias" in estimating their own risk for developing cancer, *see* 79

Fed. Reg. at 23,168, is a general summary of findings from a June 1998 American Cancer Society Conference, *see* F. Baker et al., *Health Risks Associated With Cigar Smoking*," 284 J. of the Am. Med. Ass'n 735, 737 (2000). Those findings in turn cite a telephonic survey that did not distinguish between cigar types, another article about cigarette use only, and a third article that surveyed a random sample of individuals regarding 32 different hazards. *See* F. Baker et al., *Risk perception and cigar smoking behavior* (1998); J. Stretcher et al., *Do cigarette smokers have unrealistic perceptions of their heart attack, cancer, and smoke risk?*, 18 J. Behavior Med. 45 (1995); N.D. Weinstein, *Unrealistic optimism about susceptibility to health problems: conclusions from a community-wide sample*, 10 J. Behavioral Med. 481 (1987). The cited studies thus draw no conclusions about general public or consumer perceptions about the health risks of premium cigars. Accordingly, they provide little weight to justify the FDA's extension of warning labels to premium cigars. *See* 79 Fed. Reg. at 23,143 (seeking comments as to "what provisions of the proposed ruled may be appropriate or not appropriate for different kinds of cigars").

The only study cited in the Proposed Deeming Rule that arguably supports the FDA's position is a qualitative study conducted by Health Canada that assessed the impact of cigar, pipe, and smokeless tobacco health warnings on consumers. *See id*. at 23,166 (citing Health Canada, Tobacco Control Programme, *Health Warning Messages on Smokeless Tobacco, Cigars, and Pipe Products: A Qualitative Study With Consumers*, H4097-02-5029 (2003) [hereinafter Health Canada Study]). That study found that "[m]ost large cigar smokers thought their product was less addictive than cigarettes, or not addictive at all because they smoked for pleasure, or smoked less daily." Health Canada Study at 6; *see also id.* at 36–39 (noting that all cigar users perceived cigars to be less harmful because they do not inhale and because tobacco is natural and therefore contains fewer chemicals and additives). Yet this study, too, appears to group pipe tobacco users with large

cigar users. *See id.* at 21, 36–37. And more to the point, the FDA does not rely on this study, as it was neither among the studies identified in the pages of the Proposed Deeming Rule that the Final Deeming Rule cross-referenced, nor identified in litigation. It is not the task of a reviewing court to go "rummaging through the record" in search of a basis for upholding the agency's action. *Conn. Power & Light Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 534–35 (D.C. Cir. 1982) (internal quotation marks omitted); *see also Owner-Operator Indep. Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin*., 494 F. 3d 188, 206 (D.C. Cir. 2007) ("This court may 'not attempt itself to make up for [] deficiencies: We may not supply a reasoned basis for the agency's action that the agency itself has not given.'" (quoting *State Farm*, 463 U.S. at 43)).

In summary, the FDA failed to articulate a reasoned basis for requiring warning labels for premium cigars. Despite its professed interest in "help[ing] correct current misperceptions about newly deemed products," Hr'g Tr. at 61, the agency did not separately consider whether users or prospective users of premium cigars in fact harbor misconceptions about the product or otherwise remain in the dark about the health risks attendant to premium cigar use. Instead, the agency focused only on the general "health risks of premium cigars," 81 Fed. Reg. at 29,020–27, and assumed that its findings as to the "established data on the health effects . . . of traditional large cigars" are not only "applicable to . . . premium cigars, given that they share the same characteristics and are smoked in similar ways," 81 Fed. Reg. at 29,020, but also that these health effects are a sufficient basis for requiring warning labels. That approach was inadequate. "By failing to analyze" whether consumers are in fact misinformed or underinformed as to premium cigar health effects, "the agency has failed to offer the rational connection between facts and judgment required to pass muster under the arbitrary and capricious standard." *State Farm*, 463 U.S. at 56; *see also Getty v. Fed. Savs. & Loan Ins. Corp*., 805 F.2d 1050, 1057 (D.C. Cir. 1986)

(holding that an agency must provide more than "conclusory statements" to prove it "consider[ed] [the relevant] priorities").

In reaching this conclusion, the court is mindful of what it has already held. In *Cigar Association*, this court determined that the Deeming Rule's warnings requirements survived First Amendment and APA scrutiny. *See Cigar Ass'n*, 315 F. Supp. 3d at 163, 174–75. *Cigar Association* did not, however, present the issue the court decides here, which is whether the FDA adequately justified regulation as to a particular subset of cigar product—the premium cigar. The agency asked for comments not only on whether to regulate premium cigars at all but whether the various types of regulation set forth in the Proposed Deeming Rule were appropriate for particular products. In framing the question that way, it was incumbent upon the agency to explain not only why it decided to deem premium cigars—i.e., why it selected Option 1 over Option 2—but also why the health warnings regime was appropriate for the distinct category of premium cigars products. The FDA failed in this latter task and therefore fell short of its obligation to "adequately explain its result" in violation of the APA. *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993). The court's decision in *Cigar Association* does not foreclose that determination.

C. Remedy

The only remaining question then is the appropriate remedy. When a court concludes that agency action is unlawful, "the practice of the court is ordinarily to vacate the rule." *Ill. Pub. Telecomms. Ass'n v. FCC*, 123 F.3d 693, 693 (D.C. Cir. 1997); *Sierra Club v. Van Antwerp*, 719 F. Supp. 2d 77, 78 (D.D.C. 2010) ("[B]oth the Supreme Court and the D.C. Circuit Court have held that remand, along with vacatur, is the presumptively appropriate remedy for a violation of the APA."). "[A]lthough vacatur is the normal remedy, [courts] sometimes decline to vacate an

agency's action." *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014). That decision depends on the "seriousness of the [rule]'s deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) (internal quotation marks and citation omitted); *see also Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, 282 F. Supp. 3d 91, 103–04 (D.D.C. 2017) (declining to vacate when agency "largely complied" with statute and could likely substantiate prior conclusions on remand).

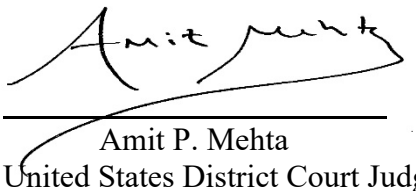
Neither of these factors warrant deviating from the ordinary remedy of vacatur in this case. The D.C. Circuit has said that the "fail[ure] to address" an important aspect of the problem is a "major shortcoming[]." *Humane Soc'y of United States v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017). It has repeatedly vacated agency actions with that flaw. *See, e.g.*, *id*. at 615; *SecurityPoint Holdings, Inc. v. TSA*, 867 F.3d 180, 185 (D.C. Cir. 2017) ("[T]he court must vacate a decision that 'entirely failed to consider an important aspect of the problem.'") (*quoting State Farm*, 463 U.S. at 43); *Wedgewood Village Pharmacy v. DEA*, 509 F.3d 541, 552–53 (D.C. Cir. 2007) (vacating after failure to consider an important aspect of the problem). Here, vacatur is appropriate because FDA did not supply a reasoned explanation for imposing the very requirement—health warnings for premium cigars—that commenters challenged. *See Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1052–53 (D.C. Cir. 2002).

Nor would vacatur be particularly disruptive. This is not a case in which "[t]he egg has been scrambled and there is no apparent way to restore the status quo ante." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002). Indeed, the warnings requirements for premium cigars have not yet gone into effect. Allowing these requirements to take effect during

remand, on the other hand, could be exceptionally disruptive for Plaintiffs and the premium cigar industry, requiring manufacturers and retailers to undertake significant compliance expenses. *See, e.g.*, J.A. Vol. 3 at 323–38. Moreover, the FDA's ongoing premium cigar rulemaking—which explicitly seeks information about health warnings requirements for premium cigars, *see* 83 Fed. Reg. at 12,904—creates the distinct possibility that the agency's approach to premium cigars and their labeling "may itself be changed," *Allied-Signal*, 988 F.2d at 151. The court therefore concludes that preserving the status quo is appropriate.

V. CONCLUSION

For the reasons set forth above, Plaintiffs' Motion for Summary Judgment, ECF No. 120, is granted and Defendants' Cross-Motion for Partial Summary Judgment, ECF No. 124, is denied. The Deeming Rule's warnings requirement for premium cigars is hereby vacated, and this portion of the Rule is remanded to the agency for further proceedings consistent with this Memorandum Opinion. A separate final, appealable order accompanies this Memorandum Opinion.



Dated: February 3, 2020

Amit P. Mehta
United States District Court Judge