UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION AND ORDER

I.

Once more, the court takes up a challenge to the U.S. Food and Drug Administration's ("FDA") regulation of a category of tobacco product known as "premium cigars." In 2016, as part of a rulemaking referred to as the "Final Deeming Rule," the FDA "deemed" premium cigars subject to the Family Smoking Prevention and Tobacco Control Act of 2009. *See* Deeming Tobacco Products to Be Subject to the FDCA, 81 Fed. Reg. 28,974, 29,020 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143). Premium cigar interest groups thereafter brought various challenges to the Final Deeming Rule and largely succeeded. This court has struck down as arbitrary and capricious the Rule's requirement that premium cigar packaging and advertising carry specified health warnings. *See Cigar Ass'n of Am. v. FDA* (*Cigar II*), 436 F. Supp. 3d 70 (D.D.C. 2020); *see also Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 2020) (striking down health-warnings mandate for all cigar products). And it has enjoined the FDA from enforcing the statutory premarket-review scheme against premium cigars because the agency failed to consider

an abbreviated, less burdensome process for premium cigars. *See Cigar Ass'n of Am. v. FDA* (*Cigar III*), 480 F. Supp. 3d 256, 261 (D.D.C. 2020).

These earlier challenges focused on particular regulatory consequences of the FDA's decision to deem premium cigars. Plaintiffs[1] now contest the deeming itself. They advance two claims. First, they assert that the FDA's decision not to exempt premium cigars altogether from regulation under the Final Deeming Rule was arbitrary and capricious (Count V of the Fourth Amended Complaint). Fourth Am. Compl., ECF No. 236, ¶¶ 166–194. Second, they maintain that the agency failed to reasonably consider the costs and benefits of subjecting small businesses within the premium cigar industry to regulation, as required by the Regulatory Flexibility Act (Count IV of the Fourth Amended Complaint). *Id.* ¶¶ 141–165.

The court agrees with the first of these contentions but not the second. Accordingly, the parties' cross-motions for summary judgment are granted in part and denied in part. The court will invite additional briefing from the parties before selecting an appropriate remedy.

II.

The background relevant to the claims at issue is as follows.[2] The Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA") authorizes the FDA to regulate the manufacture, distribution, and marketing of tobacco products. *See* 21 U.S.C. § 387a. The legislation subjected only certain tobacco products to immediate regulation—namely, "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." *Id.* § 387a(b). Regulation of other tobacco products would be at the FDA's discretion: Congress authorized the agency to "deem[]" other products subject to the TCA. *Id.*

[1] Plaintiffs are three trade groups: Cigar Association of America, Cigar Rights of America, and Premium Cigar Association (collectively, "Plaintiffs").

[2] A fuller recitation of the relevant statutory, procedural, regulatory, and judicial proceedings can be found in the court's decision in *Cigar III*, 480 F. Supp. at 261–66.

In 2014, the FDA exercised its deeming authority. It announced a rulemaking that, among other things, would subject cigar products to regulation under the TCA. *See* Proposed Rule Deeming Tobacco Products To Be Subject to the FDCA, 79 Fed. Reg. 23,142 (Apr. 25, 2014). The agency recognized, however, that a certain category of cigar products known as "premium cigars" might merit different treatment. It wrote that, "although all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars . . . may have the potential for varying effects on public health." *Id.* at 23,150. The FDA thus proposed options that "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 what it called "Option 1," the FDA would "deem all products meeting the [TCA] statutory definition of 'tobacco product,'" with some exceptions not relevant here. *Id.* Option 1, if selected, would subject premium cigars to the TCA's requirements. Conversely, "Option 2" would exclude premium cigars from the scope of the Final Deeming Rule. *Id.* at 23,145. The agency sought "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.* at 23,143.

Premium cigar interest groups accepted the FDA's invitation and urged the agency to select Option 2. One commenter's submission is illustrative. Plaintiff Cigar Rights of America ("CRA"), an advocacy group for premium cigar consumers, cited multiple reasons for selecting Option 2. It asserted that, because the "vast majority of premium cigar consumers are only occasional users (one cigar per day or less)," premium cigars do not pose the same type of public health concerns as other tobacco products. J.A., ECF No. 259 [hereinafter A.R.], J.A. – Vol. II, ECF No. 259-1 [hereinafter A.R. Vol. II], at 130340. It also posited that most premium cigar smokers "do not inhale at all," "which also substantially lowers disease risk." *Id.* at 130341.

CRA also addressed youth consumption. It wrote that smokers of premium cigars tended to be more mature adults, typically above the age of 40, and that "[t]here is still no evidence that minors use premium cigars in significant quantities." *Id.* at 130337–38.

Notwithstanding such comments, the FDA decided to deem premium cigars and selected Option 1. 81 Fed. Reg. at 28,976. The agency stated that, "despite our explicit requests," commenters "did not include data indicating that premium cigar smokers are not subject to disease risk and addiction." *Id.* at 29,024. It added that "there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." *Id.* at 29,020. With regard to youth consumption, the FDA observed that "studies indicate that [youth and young adults] are also using premium cigars." *Id.* at 29,022. Ultimately, the agency "concluded that deeming all cigars, rather than a subset, more completely protects the public health." *Id.* at 29,020.

The agency performed a Regulatory Flexibility Act analysis as part of the Final Deeming Rule. In so doing, the FDA did not undertake a specific cost-benefit analysis with regard to the selection of Option 1 over Option 2. *Id.* at 29,074–76.

III.

Plaintiffs advance three primary arguments as to why the FDA's decision to deem premium cigars was arbitrary and capricious. First, they contend that the FDA erroneously based its decision on the belief that there was no evidence in the administrative record of different usage patterns for premium cigars that might lead to different health outcomes, when in fact there was such evidence. Pls.' Mot. for Summ. J. & for a Permanent Inj., ECF No. 247 [hereinafter Pls.' Mot.], Pls.' Mem. in Supp. of Pls.' Mot., ECF No. 247-1 [hereinafter Pls.' Mem.], at 21–28. Second, they claim that the FDA's finding as to youth usage of premium cigars was premised on a flawed reading of a

particular study. *Id.* at 28–32. And finally, Plaintiffs argue that the FDA's action was fatally flawed because the agency failed to adequately explain how regulating premium cigars would promote public health. *Id.* at 33–40. The court discusses the first two of these contentions below but need not reach the third.[3]

A.

When the FDA proposed two options for regulating cigar products, it did so because of the suggestion, made by some, that "different kinds of 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." 79 Fed. Reg. at 23,150. The FDA did not concede that there were in fact such varying effects, but it acknowledged that "[s]ome have contended that usage patterns of . . . premium cigars[] can vary dramatically from usage patterns of other cigars." *Id.* at 23,151. And it admitted that "differences in patterns of use" could produce "differences in disease risks." *Id.* As a result, the FDA sought comment to ensure that the exclusion from regulation would apply, if at all, "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.* at 23,150. The agency thus signaled that evidence of different usage patterns and their public health impacts

[3] Throughout their briefing, Plaintiffs refer to and rely upon events that occurred after the FDA issued the Final Deeming Rule in March 2016, including newer studies about the use of premium cigars. *See, e.g.*, Pls.' Mem. at 24 (referencing a 2018 study by Carol Christensen); *id.* at 24 (citing the FDA's opening of a new rulemaking in 2018 on premium cigars); *id.* at 25 (referencing a new Corey study issued in 2017); *id.* at 30 (citing a 2017 study concerning premium cigar usage among youth); *id.* at 32 (pointing to a January 2020 Guidance issued by the agency). Because the court's review under the APA is limited to the record that was before the agency at the time it acted, the court has not considered these post–Final Deeming Rule events and studies. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) ("It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015))). It will be up to the FDA to decide whether to consider this more recent information on remand. *See id.* at 1908 (stating that, if the agency decides to "deal with the problem afresh" on remand, it "is not limited to its prior reasons but must comply with the procedural requirements for new agency action" (internal quotation marks omitted)).

would be a central consideration in deciding whether to exclude premium cigars from the scope of the final rule.

Despite this ask for evidence, the FDA said it received none. According to the agency, "despite [its] explicit requests in the [Notice of Proposed Rulemaking], the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction." 81 Fed. Reg. at 29,024. It made similar "no data" statements elsewhere in the Final Deeming Rule. The FDA said that "there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." *Id.* at 29,020. Similarly, it declared that "there are no data indicating that premium cigar users are not susceptible to health risks." *Id.* And, it reiterated once more, the "FDA specifically sought comment on how the potential different patterns of use for premium cigars might result in different or decreased health impacts, but no such evidence was submitted." *Id.* at 29,022.

Plaintiffs assert that these "no data" declarations—and the resulting decision to deem premium cigars—were arbitrary and capricious because, in fact, there was record evidence showing a connection between less frequent use among premium cigar smokers and reduced public health risks, which the FDA failed to consider. *See* Pls.' Mem. at 21–24. Plaintiffs point primarily to two studies. The first is a 2014 Centers for Disease Control report titled "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults—United States, 2012–2013," whose lead author was FDA scientist Catherine Corey ("the Corey study"). *See* Pls.' Mem. at 22 (citing Catherine Corey et al., *Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults—United States, 2012–2013*, 63 MORBIDITY & MORTALITY WKLY. REP. 650–54 (2014), available at A.R. 022253–57). The Corey study analyzed data from the 2012–2013 National Adult Tobacco Survey ("NATS"), a survey of over 60,000 "noninstitutionalized U.S. civilian adults aged

≥ 18 years," which specifically identified premium cigar users by self-reported brand and product quality use.[4] A.R. 022253. The data showed, according to Corey, that "[a]mong cigar smokers who usually smoked premium cigars, 3.3% reported 'every day' use, 25.6% reported 'some day' use, and 71.2% reported use 'rarely.'" A.R. 022255. In other words, only a small fraction of survey respondents who identified themselves as premium cigar users admitted to smoking on a daily basis.

The other record evidence that Plaintiffs cite is a study by the National Cancer Institute from 1998 titled "Cigars: Health Effects and Trends Monograph No. 9." Pls.' Mem. at 23 (citing NAT'L CANCER INST., CIGARS: HEALTH EFFECTS AND TRENDS MONOGRAPH NO. 9 (1998), available at A.R. 21077–324). Monograph 9 found no statistically significant difference in the "all-cause" mortality rate as between "neversmokers" and those who smoked no more than two cigars per day. A.R. Vol. II 130342–43. By contrast, among those who smoked cigars more regularly, the "all-cause" mortality rates were significantly elevated as compared to neversmokers. *See id.*

Plaintiffs contend that the Corey study and Monograph 9, taken together, supplied the data that the FDA wrongly claimed was absent from the record and failed to consider in deciding whether to deem premium cigars. Plaintiffs say that those studies were proof that premium cigar users smoke less frequently than users of other tobacco products and that such infrequent use results in substantially lower health risks.

The FDA does not contest that the Corey study and Monograph 9 were before the agency. *See* Defs.' Cross-Mot. for Summ. J., ECF No. 250 [hereinafter Defs.' Cross-Mot.], Defs.' Mem. in Opp'n to Pls.' Mot. & in Supp. of Defs.' Cross-Mot., ECF No. 250-1 [hereinafter Defs.' Mem.],

[4] NATS defined premium cigar smokers as "those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar (5) or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper." A.R. 022253.

at 14–15. Nor does it genuinely dispute Plaintiffs' contention that these studies supply data about premium cigar usage patterns and the potential public health impacts of such patterns. *See id.*

The FDA's response is instead twofold. First, it contends that, "while Plaintiffs make much of studies about premium cigar usage patterns . . . , the FDA reasonably explained that the record evidence did not show 'that these patterns result in lower health risks.'" *Id.* at 14 (internal citations omitted). Second, the agency says that an additional "flaw in Plaintiffs' claim is that even if some premium cigar smokers' usage patterns result in some lower health risks, many other premium cigar smokers use the products in ways that carry indisputably higher health risks." *Id.* at 16. Both arguments, however, face the same problem: Each is a post-hoc justification made in the context of litigation that the court cannot countenance. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co,* 463 U.S. 29, 50 (1983) ("[C]ourts may not accept appellate counsel's *post hoc* rationalizations for agency action. It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." (internal citation omitted)); *Am. Min. Congress v. EPA*, 907 F.2d 1179, 1188 (D.C. Cir. 1990) ("[W]e cannot accept post hoc rationalizations that the agency did not offer in the [Rule]." (internal quotation marks omitted)).

As to its first contention, the agency did not, as it suggests, "reasonably explain[]" that the data on premium cigar usage patterns "did not show 'that these patterns result in lower health risks.'" Defs.' Mem. at 14. Rather, it said unequivocally that "there were *no data* provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." 81 Fed. Reg. at 29,020 (emphasis added). In other words, the agency did not evaluate the data on premium cigar usage patterns and "reasonably explain" why those patterns did not reduce public health risks; instead, it said that there was no data it had to "reasonably explain" in the first place. The agency now contends that Monograph 9's finding of

no statistically significant difference in "all-cause" mortality between infrequent cigar users and nonsmokers was likely due to "the small sample size." Defs.' Mem. at 15 & n.6. But the FDA nowhere surfaced that reason for rejecting the Monograph 9 finding in the Final Deeming Rule. In addition, the agency now seeks to minimize the "all-cause" mortality finding by stating that "all-cause mortality is just one of the many health risks posed by cigars," citing other disease risks from even limited cigar use. *Id.* at 15. But in the Final Deeming Rule the agency did not examine Monograph 9's "all-cause" mortality finding, let alone reason that other health risks justified regulating premium cigars.

With respect to the agency's second contention, the purported "flaw[]" in Plaintiffs' claim (that lower usage patterns result in reduced health risks because "many other premium cigar smokers use the products in ways that carry indisputably higher health risks") is not a "flaw" the agency noted anywhere in the Final Deeming Rule. The FDA never said, for example, that notwithstanding lower usage patterns among the great majority of premium cigar smokers, regulating those products is justified to protect the small percentage of users whose frequency of use does pose health risks. Again, its response was that there was "no [] evidence" submitted "on how the potential different patterns of use for premium cigars might result in different or decreased health impacts." 81 Fed. Reg. at 29,022. The agency now tries to flip the Corey study's findings in its favor, asserting that even if only 3.3% of premium cigar users smoke every day, that translates into approximately 120,000 adults. Defs.' Mem. at 16. But even if it is accurate to say that there are tens of thousands of daily adult smokers of premium cigars, the FDA never explained why that number still merited deeming. Importantly, the agency never confronted Monograph 9's finding that even daily cigar users do not exhibit a higher "all-cause" mortality rate than nonsmokers. It is

a blackletter rule that "an agency cannot ignore evidence contradicting its position." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018). Yet that is precisely what occurred here.

It is not as if the court is faulting the FDA for failing to connect the dots between disparate data points; the connection was already drawn for them. *See Ctr. for Auto Safety v. Peck*, 751 F.2d 1336, 1355 n.15 (D.C. Cir. 1985) ("An agency need not address every conceivable issue or alternative, no matter how remote or insignificant."). Plaintiff CRA emphasized the importance of the Corey study and Monograph 9 in its submission. A.R. Vol. II at 130341. The group cited the Corey study for the proposition that "96.7% of premium cigar smokers do not smoke them every day." *Id.* It also pointed out that Monograph 9 "found that the typical occasional cigar smoker had an 'all cause' mortality ratio of 1.02, as compared to a ratio of 1.0 for nonsmokers." *Id.* at 130342. And it referenced other statistics from Monograph 9 showing that cigar smokers "are at no greater risk" of various diseases, including certain types of cancer and heart disease. *Id.* An agency, of course, is not required to respond to every comment, no matter how insubstantial. *See Thompson v. Clark*, 741 F.2d 401, 408 (D.C. Cir. 1984). But it cannot ignore "comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule [and would] cast doubt on the reasonableness of a position taken by the agency." *Home Box Off., Inc. v. FCC* (*HBO*), 567 F.2d 9, 36 n.58 (D.C. Cir. 1977). The FDA failed this basic requirement.

At oral argument, the court pressed agency counsel to identify where in the Final Deeming Rule the FDA had responded to commenters, like CRA, who asserted that less frequent premium cigar use was associated with lower health risks. *See* Hr'g Tr., ECF No. 267 [hereinafter Hr'g Tr.], at 47. Counsel identified the first three sentences of the agency's response to Comment 98. *See id.* at 52. The final rule summarized Comment 98 as follows:

> Supporters of Option 2 claimed that premium cigar smokers use cigars less frequently than cigarette and smokeless tobacco users and, therefore, premium cigars should either not be regulated or should be subject to less regulation. They relied upon a study showing that the adult prevalence of everyday or occasional use of cigarettes was 18 percent and 2.6 percent for smokeless tobacco products, compared to 2 percent for cigars, cigarillos, and little filtered cigars.

81 Fed. Reg. at 29,025. The first three sentences of the agency's response were as follows:

> Although the prevalence of cigar smoking in the U.S. population is lower than cigarette smoking, use of cigars still presents health risks. Researchers estimate that regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010. As stated in the previous response, all cigars produce toxic cigar smoke.

Id. at 29,025 (internal citations omitted). None of these statements, however, is responsive to the contention that less frequent use of premium cigars reduces the public health risks of that product. The response that "use of cigars still presents health risks" does not identify which health risks or the relationship between premium cigar use and those risks. The next sentence does specify a health risk (premature death) but quotes an annual mortality figure (9,000) that is not specific to premium cigars, thus reducing the value of that data point.

Finally, the agency's statement that "all cigars produce toxic cigar smoke" is exactly the sort of nonresponsive, circular reasoning the court faulted previously. *See Cigar II*, 436 F. Supp. 3d at 85–86. The relevant question is not whether premium cigars, like standard cigars, produce toxic cigar smoke. The FDA already knew that to be the case. *See* 79 Fed. Reg. at 23,143 (stating in the proposed rule, "all cigars are harmful and potentially addictive"); *id.* at 23,150 (same); *id.* at 23,151 (stating in the proposed rule, "[a]ll cigars, regardless of size, produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes"); *id.* at 23,170 (same). Instead, the Proposed Deeming Rule asked whether premium

cigar smokers used the product in a materially different way from non-premium cigar smokers and whether those potential differences might warrant a different regulatory approach. Simply reprising that "all cigars produce toxic cigar smoke," 81 Fed. Reg. at 29,025, does nothing to respond to the commenters or otherwise develop the conversation as required by the APA. *See HBO*, 567 F.2d at 35 (observing that the notice-and-comment requires an "exchange of views, information, and criticism between interested persons and the agency").[5]

The FDA's answer to a different comment—Comment 97—also reflects its lack of responsiveness to the data submitted about premium cigar usage patterns and health risks. The FDA summarized Comment 97 to say:

> Many comments stated that a majority of cigar users are occasional smokers (two to six cigars per week) and do not inhale (citing Refs. 69, 75). They also indicated that premium cigar use does not lead to addiction. Finally, some comments noted that occasional cigar users have not been studied in epidemiological research, *and data for the lowest level of cigar users (one to two cigars per day) do not reveal mortality rates that are significantly different from nonsmokers* (Refs. 69, 79). However, other comments included evidence suggesting increased disease risk and nicotine dependence among infrequent cigar users and those reporting they do not inhale.

81 Fed. Reg. at 29,024. "Ref. 69" is a citation to Monograph 9, *see id* at 29,026, and the italicized portion appears to be a reference to Monograph 9's "all mortality" finding highlighted by CRA. The FDA's response does not, however, grapple with that important piece of data. Its answer instead is devoted almost exclusively to rebutting the contention that premium cigar smokers face fewer health risks because they typically do not inhale. *See id.* at 29,024. The three-paragraph

[5] At oral argument, counsel for the agency further pointed to the Final Rule's citation to a Surgeon General finding "that no amount of smoking is safe." Hr'g Tr. at 58 (citing 81 Fed. Reg. at 29,020). Again, the agency already knew that to be the case at the time of the Proposed Deeming Rule. *See* 79 Fed. Reg. at 23,150 ("[A]ll cigars are harmful and potentially addictive."). Furthermore, this response barely scratches the surface of the questions the FDA itself posed: whether premium cigar smokers smoke less frequently than non-premium cigar smokers, and whether those differences lead to materially distinct health outcomes.

response to Comment 97 contains the following statements: (1) "[S]tudies have shown that cigar smoking can cause several different types of cancer even without inhalation." (2) "While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, significant risk still exists for those who do not inhale." (3) "Researchers found that the risk of stomach cancer mortality was significantly higher among cigar users who reported they did not inhale when compared to those who did not use tobacco products." (4) "Additionally, among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancer." And (5) "Mortality risks were greater with increasing number of cigars smoked per day and self-reported level of inhalation; however, primary cigar smokers reporting no inhalation still had highly elevated mortality risks for oral, esophageal, and laryngeal cancers compared to nonsmokers." The concluding sentence is this: "Regardless of whether cigar smokers inhale, they are still subject to the addictive and other adverse health effects of the product through absorption of nicotine and harmful constituents." *Id.* at 29,024–25. The only portion of the agency's answer to Comment 97 that is not explicitly linked to an inhalation-related finding is "All cigars produce toxic cigar smoke," but that is no meaningful response at all. In short, nowhere within the Comment 97 response is any consideration given to the key Monograph 9 finding that "all-cause" mortality is effectively the same for daily cigar smokers as it is for nonsmokers.

Defendants also defend the agency's response by asserting that "the FDA reasonably explained that exempting premium cigars from regulation based on current usage patterns would not be appropriate because patterns can change over time in response to regulation." Defs.' Mem. at 14 n.4 (citing 81 Fed. Reg. at 29,025). But waving away evidence of actual, current usage patterns based on the mere possibility of a change in behavior is not reasoned decisionmaking. *See Ariz. Pub. Serv. Co. v. United States*, 742 F.2d 644, 649 n.2 (D.C.Cir.1984) ("[M]ere

conjecture and abstract theorizing offered in a vacuum are inadequate to satisfy us that the agency has engaged in reasoned decisionmaking.").

Finally, the FDA argues that this court in an earlier ruling already held that the agency had adequately addressed comments suggesting that premium cigar usage patterns result in lower health risks. Defs.' Mem. at 13 (citing *Cigar II*, 436 F. Supp. 3d at 84–85). The agency, however, overreads the court's prior decision. The agency cites portions of the court's ruling holding that the FDA had not sufficiently justified adopting a health-warnings requirement for premium cigar packaging and advertising. *See id.* In that discussion, the court stated that "[t]he Final Deeming Rule rejected commenters' arguments that the patterns of use and demographic data for premium cigars support exempting the product from regulation," and the agency's responses to commenters "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." *Cigar II*, 436 F. Supp. 3d at 85. Thus, the court's ruling was that the FDA had understood and addressed concerns raised by commenters about the accuracy of the proposed warning labels. *See id.* at 84 (framing the first contention against the warning labels requirement as "premium cigars present insufficient health concerns and thus render the warnings inaccurate as to premium cigars"). The court did not say that the FDA had adequately considered record evidence suggesting that infrequent use of premium cigars posed less public health risk.

In the end, instead of addressing the relevant data before it, the agency resorted to a common refrain to obscure the issue: "[T]here were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." 81 Fed. Reg. at 29,020. That statement was not accurate then, and despite litigation counsel's efforts, it is not accurate now. Where, as here, an agency speaks in absolute terms that

there is no evidence, it acts arbitrarily and capriciously when there is in fact pertinent record evidence and the agency ignores or overlooks it. *See County of Los Angeles v. Shalala*, 192 F.3d 1005, 1023 (D.C. Cir. 1999) ("[T]o say that she had 'no evidence' . . . runs counter to the evidence before the agency and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." (internal citation and some internal quotation marks omitted)); *Stellar IT Sols., Inc. v. USCIS*, No. 18-cv-2015 (RC), 2018 WL 6047413, at *9 (D.D.C. Nov. 19, 2018) ("[T]he agency cannot base its decision on a supposed lack of evidence when evidence was not actually lacking.").

B.

The court briefly turns now to Plaintiffs' second claim, which is that the FDA misinterpreted key evidence about premium cigar use among youth in the Final Deeming Rule. In response to comments about youth usage (Comment 92), the agency said that, "[a]lthough youth and young adults tend to smoke mass market cigar brands, they are also using premium cigars." 81 Fed. Reg. at 29,023. In support of that statement, the FDA cited a study authored by Christine Delnevo that found "3.8 percent of youth aged 12 to 17 . . . identified certain premium cigars to be the brand they smoked most often." 81 Fed. Reg. at 29,023 (citing C. Delnevo et al., *Preference for Flavoured Cigar Brands Among Youth, Young Adults and Adults in the USA*, 24 TOBACCO CONTROL 389 (2015), available at A.R. 20897–902). Plaintiffs argue that the FDA grossly misread the Delnevo study. Pls.' Mem. at 30; Pls.' Reply, ECF No. 256 [hereinafter Pls.' Reply], at 19–20. In reality, they say, the percentage of youth that reported that a premium cigar was their brand of choice was far smaller than 3.8 percent. That is because the 3.8 percent figure represents the percentage of youth in the 12-to-17 age cohort that self-identified as having smoked a premium cigar brand within the last 30 days. But only 3.3 percent of the overall sample in that age category

reported smoking *any cigar product* in the last 30 days. So, the actual percentage of premium cigar users among the surveyed 12-to-17-year-old group was 3.8 percent of the 3.3 percent who reported smoking any cigar product within the last 30 days. Thus, the Delnevo study, Plaintiffs contend, found that "only **0.1 percent** of persons aged 12-17 are premium cigar smokers." Defs.' Mem. at 30.

The court agrees with Plaintiffs' reading of the Delnevo study. And so too does the FDA. It says in its brief that "the Delnevo study . . . found that 3.8% of 12- to 17-year-olds who had smoked a cigar in the past 30 days—constituting 3.3% of that age group nationwide—most often smoked a premium cigar brand." Defs.' Mem. at 17. The agency extrapolates those percentages to the U.S. youth population of 25,000,000 and states that "the study implies that some 31,350 U.S. youth are current premium cigar smokers." *Id.* Thus, the FDA concedes that the Delnevo study shows that only 0.1 percent of youth (31,350/25,000,000) ages 12 to 17 have smoked a premium cigar within the last 30 days.

Yet, the Final Deeming Rule obscures the real math. The agency's discussion starts with this finding: "Although youth and young adults tend to smoke mass market cigar brands, they are also using premium cigars." 81 Fed. Reg. at 29,023. The next three sentences summarize the Delnovo study's findings. The first states that, "In one study, researchers used data from the 2010-2011 [National Survey on Drug Use and Health] and Nielsen market scanner date to define a study sample consisting of 6,678 past 30-day cigar smokers who reported smoking a usual brand of cigars." *Id.* The next says, "While many youth identified a mass market cigar as the brand they used most often, this analysis reveals that 3.8 percent of youth aged 12 to 17 and 12.1 percent of young adults aged 18 to 25 also identified certain premium cigars to be the brand they smoked most often." *Id.* And the third sentence reasserts the agency's conclusion: "Individuals in both

cohorts reported at least eight different premium cigar brands among the brands they used most often, providing evidence that youth and young adults are smoking premium cigars." *Id.* All of these statements are accurate, but the reasonable reader would not be off base in understanding them to imply that a more-than-negligible number of youth smoke premium cigars. Nowhere did the agency say what it now admits: that only 3.8 percent of the only 3.3 percent of youth who reported smoking a cigar within the last 30 days, or 0.1 percent of all youth, identified a premium cigar as their preferred brand. And it never extrapolated these percentages to the entire U.S. youth population, as it does now in litigation.

The court need not, however, decide whether the FDA misunderstood the Delnevo study in finding that youth "are using premium cigars" and therefore acted arbitrarily and capriciously. 81 Fed. Reg. at 29,023. The court trusts that any action by the agency on remand will view the Delnevo study in its proper light.

IV.

The court turns now to Plaintiffs' challenge to the FDA's cost-benefit analysis under the Regulatory Flexibility Act ("RFA"). According to Plaintiffs, "the FDA relied on the cost-benefit analysis" in the Final Deeming Rule to justify its selection of Option 2, "which in turn makes it subject to the requirements of the APA." Pls.' Reply at 36. Yet, the agency failed to conduct a specific cost-benefit analysis respecting this choice, separate and apart from the analysis it performed for the Final Deeming Rule as a whole. Pls.' Mem. at 41. Plaintiffs assert that "[t]he costs of regulating premium cigars were not reasonably analyzed" and the FDA failed to meaningfully engage in any effort to show the benefits were worth the costs that deeming would impose on small premium cigar manufacturers and businesses. *Id.*

But Circuit precedent confirms that the FDA was not required to perform a separate RFA analysis for its selection of Option 2. In *Cigar Association of America v. FDA*, the D.C. Circuit rejected a similar RFA challenge brought by these Plaintiffs. It held that the agency was not required "to consider the benefits . . . specifically for each industry or product affected by the Deeming Rule." 5 F.4th 68, 76 (D.C. Cir. 2021). The Circuit also said that the FDA's analysis was not required to "take a particular form." *Id.* That ruling affirmed this court's prior decision, in which it stated that "there is no legal support for the proposition that every product or industry affected by a rulemaking is entitled to a separate cost-benefit analysis." *Cigar III*, 480 F. Supp. 3d at 277 (quoting *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 407 (D.D.C. 2017)). This court also rejected "the assumption that the FDA was required to individually analyze the benefits for premium cigars." *Id.* at 277 n.12. To be sure, as Plaintiffs point out, the court's prior "conclusion was not in the context of the deeming decision." Pls.' Reply at 37. But the D.C. Circuit's ruling squarely forecloses Plaintiffs' contention that the agency was required to conduct a separate RFA analysis with respect to the deeming of any particular product—here, premium cigars.

V.

That leaves the court with the question of remedy. At oral argument, Plaintiffs pressed the court to vacate the FDA's decision to deem premium cigars. Hr'g Tr. at 21–25. The agency, on the other hand, urged the court to remand without vacatur. *See id.* at 66 (arguing that, "if the Court were to find that one justification were inadequately explained, this would be a classic case for remand without vacatur"). The court declines, however, to make a choice at this time because the parties have not briefed the issue.

IV.

For the foregoing reasons, Plaintiffs' Motion, ECF No. 247, and Defendants' Cross-Motion, ECF No. 250, are both granted in part and denied in part. The parties shall file briefs of no more than ten pages on the question of the appropriate remedy by July 26, 2022.

Dated: July 5, 2022

Amit P. Mehta
United States District Court Judge