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

I.

The court (at long last)[1] returns to this long-running dispute over the U.S. Food and Drug Administration's ("FDA") decision to regulate, or "deem," premium cigars under the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"). In July of 2022, the court held that the FDA's decision to deem premium cigars was arbitrary and capricious insofar as the agency failed to consider data before it concerning the use of premium cigars and the health effects of such use. *Cigar Ass'n of Am. et al. v. U.S. Food & Drug Admin. (Cigar IV)*, 2022 WL 2438512 (D.D.C. July 5, 2022). Because the issue of remedy had not been briefed, the court reserved on that question and invited further briefing from the parties. Since then, Plaintiffs have asked the court to vacate the FDA's decision to deem premium cigars. The FDA, on the other hand, has urged the court to remand without vacatur.

[1] The court apologizes to the parties for the length of time it has taken to issue this decision.

For the reasons that follow, the court finds that this case does not present the "exceptional" circumstances that would warrant deviating from the ordinary rule of vacatur of an arbitrary and capricious rule. Accordingly, the court vacates the FDA's decision to deem premium cigars.

II.

The court need not recite the lengthy procedural history of this case, which has been summarized in prior opinions.[2] Instead, the court will limit its discussion to the facts relevant to this decision on remedy.

In 2014, although the FDA announced a rule proposing to "deem all products meeting the [TCA's] statutory definition of 'tobacco product,'" *Proposed Rule Deeming Tobacco Products to Be Subject to the FDCA*, 79 Fed. Reg. 23,142, at 23,143 (Apr. 25, 2014), it left open the possibility of not deeming premium cigars. The agency instead proposed two options, one that would deem premium cigars and one that would not. *Id.* The FDA then sought "comment on [the two] options 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. Notwithstanding the many comments received by the agency encouraging exempting premium cigars, the FDA decided to deem them. *See Deeming Tobacco Products to Be Subject to the FDCA*, 81 Fed. Reg. 28,974, at 28,976 (May 10, 2016) ("Final Deeming Rule").

The initial challenges in this case concerned the regulatory consequences of the FDA's decision. For instance, the court vacated that portion of the Final Deeming Rule requiring premium cigars to display health warnings on packaging and advertisements. *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). The court

[2] *See, e.g.*, *Cigar Ass'n of Am. v. U.S. Food & Drug Admin. (Cigar III)*, 480 F. Supp. 3d 256 (D.D.C. 2020).

also enjoined the FDA from enforcing a statutory premarket-review scheme against premium cigars because the agency failed to consider a shortened, less burdensome process for those products. *See Cigar Ass'n of Am. v. FDA* (*Cigar III*), 480 F. Supp. 3d 256, 261 (D.D.C. 2020).

Eventually, Plaintiffs contested the deeming itself, and the court found that decision to be arbitrary and capricious. *Cigar IV*, 2022 WL 2438512. As the court explained, one of the central questions in the rulemaking process was whether "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." 2022 WL 2438512 at *3 (quoting 79 Fed. Reg. at 23,150). The agency acknowledged that "differences in patterns of use" could produce "differences in disease risks," and knew that "[s]ome have contended that usage patterns of . . . premium cigars[] can vary dramatically from usage patterns of other cigars." *Id.* (quoting 79 Fed. Reg. at 23,151). The public comment process, therefore, sought to ensure that the adopted rule 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.* (quoting 79 Fed. Reg. at 23,150).

A robust commentary about the merits of deeming premium cigars followed, yet the agency failed to consider it fully. In the Final Deeming Rule, the FDA determined that, notwithstanding "[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. The agency also asserted 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. And, it stated, 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. This court found these assertions not supported by the record. The court explained that there *was* data about different usage patterns for premium cigar users in the record,[3] but that the agency simply ignored it. That included evidence that "daily cigar users do not exhibit a higher 'all-cause' mortality rate than nonsmokers." *See Cigar IV*, 2022 WL 2438512 at *5. The court therefore held that the FDA erred in failing to consider the data addressing the central question of usage patterns and attendant health risks. *Id.* at *7.

The court also criticized the agency's representations about premium cigar use among youth. *Id.* at *8. The court observed that the agency had, strictly speaking, accurately described findings of a key study about premium cigar usage among youth, but it had "obscure[d] the real math." *Id.* The court observed that "the reasonable reader would not be off base in understanding [the FDA's description of the study] to imply that a more-than-negligible number of youth smoke premium cigars," when in fact a miniscule percentage do. *Id.* ("[O]nly 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."). The court did not need to make an arbitrary and capricious finding regarding youth usage—because it had already found the deeming itself unlawful—but urged the agency to "view [the study] in its proper light" when taking future action. *Id.*

Since the court's decision in *Cigar IV*, the parties have each filed remedies briefs addressing the appropriateness of vacatur. *See* Defs.' Remedy Br., ECF No. 270 [hereinafter

[3] *See Cigar IV*, 2022 WL 2438512 at *3 (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) (demonstrating that only a small fraction of survey respondents who identified themselves as premium cigar users admitted to smoking on a daily basis); NAT'L CANCER INST., CIGARS: HEALTH EFFECTS AND TRENDS MONOGRAPH NO. 9 (1998) (finding no statistically significant difference in the "all-cause" mortality rate as between "neversmokers" and those who smoked no more than two cigars per day)).

Defs.' Br.]; Suppl. Mem. in Supp. of Vacating the FDA's Regulation of Premium Cigars, ECF No. 271 [hereinafter Pls.' Br.]. Plaintiffs[4] have also provided additional information to the court in a supplemental brief, Pls.' Notice of Intervening Events and Authority, ECF No. 274 [hereinafter Pls.' Suppl. Br.], and Defendants have filed a supplemental brief in response, Defs.' Resp. to Notice of Suppl. Auth., ECF. No. 275 [hereinafter Defs.' Suppl. Br.].

III.

A plaintiff who "prevails on its [Administrative Procedure Act ("APA")] claim" is "entitled to relief under that statute, which normally will be a vacatur." *Am. Bioscience Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001); 5 U.S.C. § 706. The D.C. Circuit has "made clear that 'when a reviewing court determines that the agency regulations are unlawful, the ordinary result is that the rules are vacated.'" *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs.*, 145 F.3d 1399, 1409 (D.C. Cir. 1998); *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.").

While remand without vacatur is an available remedy, it is generally reserved for "exceptional" circumstances. *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 519 (D.C. Cir. 2020). A court's decision to remand without vacatur depends upon consideration of two factors: (1) "the seriousness of the [rule's] deficiencies," and (2) "the disruptive consequences of vacating the rule." *Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017). The burden to demonstrate such extraordinary circumstances lies with the government. *See CBOE Futures Exch., LLC v. Sec. & Exch. Comm'n*, __ F.4th __, 2023 WL 4832068 (D.C. Cir. July 28, 2023); *Friends of the Earth v. Haaland*, 583 F. Supp. 113, 156 n.29 (D.D.C. 2022).

[4] The supplemental brief was submitted by two of the three Plaintiffs, Premium Cigar Association and Cigar Rights of America. *See* Pls.' Suppl. Br.

IV.

The FDA argues that both the Final Deeming Rule's minimal deficiencies and the disruptive consequences of vacatur weigh in favor of remand without vacatur. Defs.' Br. at 7–15. Regarding the seriousness of the rule's deficiencies, the agency argues that the agency likely can cure the defect identified by the court by addressing existing record evidence on remand. *Id.* at 13–15. Regarding the disruption, the FDA posits that the public health harms and potential litigation over reallocation of user fees support remand without vacatur. *Id.* at 7–13. The court finds neither argument persuasive.

A.

As to the first factor, the agency makes two arguments. First, it says, "the FDA can readily cure the error found by the Court on remand by adequately addressing the record evidence on premium cigar usage patterns and the health risks associated with those patterns." Defs.' Br. at 14. Second, it asserts, the court did not disturb the agency's other rationales for deeming premium cigars, and the agency on remand could elaborate on these rationales. *Id.* at 15. Those reasons include: (1) the FDA's concern[] about" "dual and polyuse of cigars and other tobacco products" "common among both adults and youth"; (2) the fact that "[a]ll cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders"; and (3) the FDA's finding that record evidence "clearly illustrates that young adults are using premium cigars." *Id.* The FDA thus asserts that its "failure to discuss the studies concerning usage patterns" was "harmless." *Id.*

The D.C. Circuit has said that "the court must vacate a decision that 'entirely failed to consider an important aspect of the problem.'" *SecurityPoint Holdings, Inc. v. TSA*, 867 F.3d 180, 185 (D.C. Cir. 2017) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto.*

Ins. Co., 463 U.S. 29, 43 (1983)). And it has "not hesitated to vacate a rule when the agency has not responded to empirical data or to an argument inconsistent with its conclusion." *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009). Both principles apply here. The central question the FDA faced in deciding whether to deem was "whether [premium] cigar smokers used the product in a materially different way from non-premium cigar smokers and whether those material differences might warrant a different regulatory approach." *Cigar IV*, 2022 WL 2438512 at *6. The agency then ignored relevant data in the record that commentors had highlighted and inexplicably made a "no data" finding. 81 Fed. Reg. at 29,020–24. The significance of the agency's error supports vacatur.

Nor is it certain, as the FDA suggests, that on remand it would again deem premium cigars. Relevant new evidence has emerged in the years since the agency's action. Most notably, in 2021, the FDA contracted with the National Academies of Sciences, Engineering, and Medicine (NASEM) "to conduct a comprehensive and systematic assessment and review of the scientific literature and provide a final report of the study results" concerning the usage patterns and health effects of premium cigar smoking.[5] In March 2022, the NASEM released its report, and it contains important findings that may bear on the deeming question. *See, e.g.*, Pl.'s Supplemental Mem., ECF No. 265, Ex. A, ECF No. 265-1 (NASEM report), at 11–13, 15–18. On remand, the agency "may wish" to consider this and other new evidence and seek comment before acting. *Union Elec. Co. v. FERC*, 890 F.2d 1193, 1196 (D.C. Cir. 1989). The court will not hazard a guess at how the agency would come out if it were to consider new evidence.

[5] U.S. Food and Drug Admin., CTP Statement on Withdrawal of the Unified Agenda Entry Pertaining to the Advance Notice of Proposed Rulemaking for Premium Cigars and Related Request for Information (June 11, 2021) (available at https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-statement-withdrawal-unified-agenda-entry-pertaining-advance-notice-proposed-rulemaking-premium).

As to the FDA's second contention that on remand it could amplify the other reasons for having deemed premium cigars, Defs.' Br. at 15, the problem there is that each of those other reasons cannot be divorced from the central failure to consider data on usage patterns and health effects. For instance, the agency's concern about "dual and polyuse" of premium cigars and other tobacco products is directly related to usage patterns and health effects. Similarly, the agency's determination that "young adults are using premium cigars," which the court criticized for "obscur[ing] the real math," is itself a statement about usage. And the agency's rationale that "all cigars produce secondhand smoke" cannot be viewed apart from the data on the smoking habits and health impacts on premium cigar users. The agency's failure to "consider an important aspect of the problem" cannot be rescued by these other rationales. *SecurityPoint Holdings*, 867 F.3d at 185.

B.

The second factor the court must consider is the "disruptive consequences" of vacating the rule. *Humane Soc'y*, 865 F.3d at 614. The FDA makes three primary arguments.

First, the FDA emphasizes "[v]acating the deeming rule as it applies to premium cigars would leave that category of tobacco products entirely unregulated at the federal level." Defs.' Br. at 8. That means it would be legal under federal law to sell premium cigars to young adults under age 21; to distribute premium cigars in vending machines and as free samples; and that restrictions on false or mislabeling labeling and advertising could not be enforced. *Id.* Second, the agency asserts that maintaining the status quo will not impose significant burdens on premium cigar manufacturers. *Id.* at 9–10. And third, the FDA argues that vacatur here would invite litigation about the agency's user fee scheme, which funds the regulation of all tobacco products.

Id. at 10–13. The court does not discount the importance of any of these consequences, but they do not, either alone or in combination, warrant remand without vacatur.

Public Health Harms. With respect to impact on public health, the FDA starts with the fact that vacatur would mean premium cigar sales to youth under the age of 21 will no longer be unlawful under federal law. But this concern is mitigated by the fact that existing state laws limit sales to youth and minors. Pls.' Br. at 8. For example, all 50 states prohibit the sale of premium cigars to persons under 18 years old. Pls.' Reply in Supp. of Pls.' Mot. for Summ. J., ECF No. 256, at 30 n.10. Additionally, all but 12 states and four territories prohibit their sale to 18- to 20-year-olds.[6] Although state laws will not bar sales to all young adults under 21, vacatur will make premium cigars newly legally available to only a small segment of the population.

As for the availability of machine vending and free samples of premium cigars, the FDA has not shown to what extent premium cigars are distributed in those ways, particularly to reach young adults and minors. *See* 81 Fed. Reg. at 29,054 (stating that restricting free samples of premium cigars "will eliminate a pathway for youth to access tobacco products"). Given the higher individual cost of a premium cigar, it is unlikely that premium cigars are commonly sold through vending machines. And, presumably, the same state laws that restrict sales of tobacco products to youth under 18 or 21 also prohibit giving those products away for free as samples to youth.

Finally, although limiting the FDA's ability to enforce the law as to false or misleading labeling of premium cigar products is a legitimate concern, the agency has not shown that there is a history of mislabeling products in the premium cigar industry. The FDA has given the court no reason to think that its inability to police false or misleading labeling is likely to open the floodgates to mislabeled premium cigars. Additionally, in a different context, the FDA has said

[6] *See* Defs.' Br. at 8 (citing U.S. Ctrs. for Disease Control and Prevention, STATE System Minimum Legal Sales Age (MLSA) Laws for Tobacco Products Fact Sheet (last visited July 31, 2023), https://perma.cc/8QK8-8P23).

that premium cigars are its "lowest [enforcement] priorit[y]" relative to other tobacco products used with greater frequency by youth. *See* FDA's August 2020 Notice to Court, ECF No. 209, at 3 (stating that premium cigars were the agency's lowest enforcement priority with respect to the premarket authorization requirement). The agency has not said otherwise with respect to the labeling of premium cigars.

Burdens on Premium Cigar Manufacturers. The FDA also argues that preserving the status quo would *not* impose significant burdens on premium cigar manufacturers. The agency points out that the most onerous requirements brought about by the Final Deeming Rule—the health warnings requirements and premarket review—have been vacated or enjoined as to premium cigars. Defs.' Br. at 9. And the reporting requirements triggered by the deeming decision are one-time obligations that do not impose significant ongoing costs. *See id.* at 4 & n.1.

But Plaintiffs point to other burdens of ongoing regulation. Plaintiffs emphasize that the Final Deeming Rule has caused difficulty with respect to bringing new products to market, and there is the ever-present possibility of increased regulatory burdens. Pls.' Br. at 9. For example, in the event of remand without vacatur, the agency could subject Plaintiff manufacturers to Harmful and Potentially Harmful Constituent ("HPHC") testing. *Id.* at 11. While such testing is not currently in effect, Plaintiffs have shown that the possibility of future HPHC testing and other regulation has resulted in "[s]everal premium cigar manufacturers . . . abstaining from investments in new products, plants, and employees," due to fears that regulatory expenses will bankrupt their companies. *Id.* (citing Patel Decl. ¶¶ 11–14; Padrón Decl. ¶¶ 5–8). Plaintiffs explain that "creating a premium cigar product can take a half-decade or more from the decision to make a premium cigar to putting it on the shelf," making regulatory uncertainties a barrier to entry and production in the industry. *Id.* (citing Patel Decl. ¶ 12; Padrón Decl. ¶ 6).

Moreover, in their supplemental brief, Plaintiffs note that, on March 10, 2023, the FDA "proposed a sweeping new rule prescribing the smallest details of manufacturing tobacco products," which could apply to premium cigars, absent vacatur. Pls.' Suppl. Br. at 2–5 (citing *Requirements for Tobacco Product Manufacturing Practice*, 88 Fed. Reg. 15,174 (Mar. 10, 2023) (to be codified at 21 C.F.R. § 1120)). While this rule is not final, and thus its ultimate impact speculative, allowing the Final Deeming Rule to remain in place could expose premium cigar manufacturers to more costly and burdensome regulation.

Fee Scheme. Finally, the FDA anticipates that Plaintiffs will argue that vacatur means they are no longer obligated to pay the user fees imposed by the TCA. *See* Defs.' Br. at 10. As a result, the FDA expects it will face litigation from other regulated tobacco product manufacturers if it tries to shift costs to them, and the agency may need to engage in rulemaking if it must devise a new method to calculate user fees. *See* Defs.' Br. at 10–13.

These are fair concerns. Ultimately, however, it is the agency's burden to demonstrate that the disruptive consequences of vacatur warrant displacing the default remedy. *See CBOE Future Exch.*, ___ F.4th at ___ (declining to remand without vacatur because the defendant had "not shown that vacatur would be so disruptive as to justify a departure from our normal course"). The court must weigh the potential regulatory consequences against the fact that premium cigar manufactures are annually paying an estimated $15–$20M in user fees, even though FDA's deeming decision did not follow the APA in the first place. *See* Pls.' Br. at 10 (citing Patel Decl. ¶ 10; Padrón Decl. ¶ 10). On balance, the future fallout that the FDA may face from vacatur does not outweigh the financial and other burdens the premium cigar industry has had to shoulder while subject to the Final Deeming Rule.

IV.

For the foregoing reasons, the FDA's Final Deeming Rule is vacated insofar as it applies to premium cigars.[7]

Dated: August 9, 2023

Amit P. Mehta
United States District Court Judge

[7] For purposes of this ruling, premium cigars are those cigars that: (1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than 6 pounds per 1,000 units. *See Cigar Ass'n III*, 480 F. Supp. 3d at 281.