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.	)	

ORDER

Plaintiffs Cigar Association of America, International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America seek declaratory relief on Count X of their Amended Complaint. Pls.' Mem. in Support of Partial Summ. J. on Count X of the Am. Compl. and for a Declaration, ECF No. 136 [hereinafter Pls.' Mot.]. For the reasons that follow, Plaintiffs' motion is denied without prejudice.

I.

The court declines to grant declaratory relief for three principal reasons.

A.

First, Plaintiffs have not satisfied their burden to establish standing. "The fact that [Plaintiffs] seek[] a declaratory judgment does not obviate [their] need to show standing." *Grand Lodge of the FOP v. Ashcroft*, 185 F. Supp. 2d 9, 15 n.4 (D.D.C. 2001). Accordingly, Plaintiffs must show the "irreducible constitutional minimum" of Article III standing: (1) injury in fact, (2) causation, and (3) redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Here, Plaintiffs fail on both the causation and redressability prongs: they have failed to allege an

injury that is "fairly . . . trace[able] to the challenged action of the defendant," *id.* at 590 (internal quotation marks and citation omitted), and they have not shown that "the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged," *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663–64 (D.C. Cir. 1996) (en banc) (footnote omitted). That is because the predicament in which Plaintiffs find themselves—facing an earlier deadline to comply with a new statutory substantial equivalence requirement—was caused not by any action or inaction by the Food and Drug Administration ("FDA"); rather, it is entirely a function of a judicial ruling. Plaintiffs effectively concede as much. *See* Pls.' Mot. at 1 (stating that the reason they seek relief before this court is "because of a recent opinion").

In *American Academy of Pediatrics* ("*AAP*") *v. FDA*, No. 18-883 (D. Md.), the court vacated the FDA's August 2017 Guidance, *see AAP v. FDA*, 379 F. Supp. 3d 461, 498 (D. Md. 2019), in which the agency had announced an extension of the substantial equivalence deadline for newly deemed products to 2021 for cigar and pipe tobacco products and to 2022 for e-cigarettes and e-cigars. The *AAP* court held that the agency had abused its discretion by extending the statutory deadline, *id.*, and, in a later remedial ruling, ordered the agency to implement the substantial equivalence requirement for all newly deemed products within ten months, *see AAP v. FDA*, No. 18-883, 2019 WL 3067492, at *7 (D. Md. July 12, 2019). The court made no exception for cigar and pipe tobacco products. Thus, the *AAP* court's decision is the cause of Plaintiffs' claimed harm, not any agency action. Correspondingly, Plaintiffs' requested relief—a declaration from this court that the August 2017 Guidance remains in effect for Plaintiffs and its members—cannot remedy the alleged injury. Such an order would be tantamount to permitting a collateral attack on the *AAP* court's order, which this court cannot do. *See McNeil v. Brown*, No. 17-CV-2602, 2018 WL 4623057, at *7 (D.D.C. Sept. 26, 2018) (observing that "federal district courts

lack the power to void or otherwise alter other federal courts' orders through a collateral attack"). Because *AAP* vacated the FDA's guidance wholesale, and the FDA remains bound by the *AAP* court's decision unless an appeal overturns the decision, this court cannot issue a declaration in this case altering that reality.

Plaintiffs offer an array of arguments to the contrary, none persuasive. They contend that the "unlawful conduct" causing their injury is the FDA's future decision to declare Plaintiffs' products misbranded, should those products enter the market without first going through substantial equivalence process. *See* Hr'g Tr. at 11–12. But this anticipated down-the-line injury is too speculative to confer standing. *See Arpaio v. Obama*, 797 F.3d 11, 21 (D.C. Cir. 2015) ("When considering any chain of allegations for standing purposes, we may reject as overly speculative those links which are predictions of future events . . . ." (internal quotation marks omitted)).

Plaintiffs' attempt to read *AAP* as excluding cigars and pipe tobacco—and therefore not the cause of their injury—is likewise unavailing. The August 2017 Guidance expressly "applie[d] to all categories of newly regulated products that were on the market on August 8, 2016, including [e-cigarettes and e-cigars], hookah, pipe tobacco, and cigars." FDA, Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, at 3 n.3 (Aug. 2017). The parties and the court in *AAP* referenced cigars throughout the litigation, *see, e.g.*, *AAP* ECF No. 36-1; cigar manufacturers filed an amicus brief advancing their position, *see AAP* ECF No. 113; and the court's order vacating the Guidance not only notes that the FDA's Guidance applies to cigars, *see, e.g.*, *AAP*, 379 F. Supp. 3d at 472, it declares broadly that "the August 2017 Guidance must be vacated," *id.* at 498. What is more, when Plaintiffs sought clarification from the *AAP* court as to the breadth of its rulings, that court made clear that its

remedial order applies to cigars and pipe tobacco. *See* Notice of Suppl. Authority, Ex. 1, ECF No. 157-1 at 5–7. Accordingly, there is no carve-out for cigars or pipe tobacco in *AAP*'s remedial order.

B.

Second, the novel declaration that Plaintiffs seek is not premised on any claimed violation of law by the FDA, or by the FDA's failure to take required action. The requested declaration would require the court to evaluate the merits of the very action that Plaintiffs wish to have declared valid, i.e., the propriety of Plaintiffs' desired substantial equivalence deadline. Yet, Plaintiffs have not made an argument as to the FDA's power to set a different substantial equivalence deadline than that set by Congress. And in any event, taking up that question would, as discussed, collaterally challenge the court's decision in *AAP*, which held that the agency lacks such authority. "The availability of declaratory relief presupposes the existence of a judicially remediable right." *C & E Servs., Inc. of Washington v. D.C. Water & Sewer Auth*., 310 F.3d 197, 201 (D.C. Cir. 2002) (cleaned up). Here, Plaintiffs have identified none.

C.

Third, "equitable" and "prudential" factors counsel against awarding declaratory relief. *See Glenn v. Fay*, 222 F. Supp. 3d 31, 35 (D.D.C. 2016). A district court may consider a number of factors when assessing whether to grant declaratory relief, including, among others, whether other remedies are available, the conduct of the party seeking relief, and "the degree of adverseness between the parties." *Hanes Crop. v. Millard*, 531 F.2d 585, 591 n.4 (D.C. Cir. 1976).

All of these factors weigh against Plaintiffs. Other remedies have been available to Plaintiffs for some time—namely, seeking relief before the court in *AAP*. But Plaintiffs chose not pursue intervention in *AAP* at the start, and they ultimately did so only after the court had vacated

the August 2017 Guidance and had asked the parties for briefing on remedies. *See AAP* ECF No. 135; *AAP* ECF No. 140. Because Plaintiffs delayed in raising their concerns before the *AAP* court, their conduct weighs against granting the extraordinary relief they now request. *Cf. Swish Mktg., Inc. v. FTC*, 669 F. Supp. 2d 72, 78 (D.D.C. 2009) ("[I]n examining whether to resolve a declaratory judgment action, courts take a dim view of declaratory plaintiffs who file their suits mere days or weeks before the coercive suits filed by a 'natural plaintiff' and who seem to have done so for the purpose of acquiring a favorable forum.") (internal quotations marks omitted). Moreover, as the FDA and amici point out, Plaintiffs and the FDA are not "adverse" on this issue—they agree that the August 2017 Guidance was a permissible exercise of agency enforcement discretion.

As the foregoing equitable factors militate against granting Plaintiffs' request for a declaratory judgment, the court exercises its discretion in declining declaratory relief.

II.

For the foregoing reasons, the court denies without prejudice Plaintiffs' Motion for Partial Summary Judgment on Count X and for a Declaration, ECF No. 136.

Dated: October 18, 2019

Amit P. Mehta
United States District Judge