UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION AND ORDER

I.

In a Memorandum Opinion and Order issued on August 19, 2020, the court granted summary judgment in favor of Defendants on Counts I, XI, XIII, and XV of the Amended Complaint. *See* Mem. Op. & Order, ECF No. 214 [hereinafter Mem. Op.]. Soon thereafter, on August 24, 2020, the court entered a final judgment as to these counts (and others) pursuant to Federal Rule of Civil Procedure 54(b) to facilitate an appeal of the court's rulings. *See* Order, ECF No. 217. Two days later, Plaintiffs Premium Cigar Association of America, Premium Cigar Association, and Cigar Rights of America filed a notice of appeal. *See* Pls.' Notice of Appeal, ECF No. 219. Now, one of the plaintiffs, Cigar Association of America, seeks an injunction pending appeal "against the application of the premarket review requirements of the Final Deeming Rule to cigar and pipe tobacco manufacturers" pursuant to Rule 62(d), "pending resolution of any appeal arising from the Court's August 19, 2020 order granting summary judgment for the Government on Counts I, XI, XIII, and XV of the Amended Complaint for 90 days thereafter." Pl.'s Mot. for a Stay, ECF No. 216 [hereinafter Pl.'s Mot.]. Alternatively,

Plaintiff asks the court to grant relief under 5 U.S.C. § 705, which authorizes a court reviewing an action brought under the Administrative Procedure Act ("APA") to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." *Id.* at 2 (quoting 5 U.S.C. § 705). The court has considered the grounds advanced for the relief requested, and for the reasons that follow, Plaintiff's motion is denied.

II.

The procedural and substantive history of this case is set out in detail in the court's Memorandum Opinion and Order, and as time is of the essence, the court does not repeat it here. In additional the court comprehensively described the sliding-scale standard for an injunction pending appeal in *Cigar Association of America v. U.S. Food and Drug Administration* ("*Cigar I*"), 317 F. Supp. 3d 555 (D.D.C. 2018), and in the interest of efficiency, incorporates that standard and applies it in this decision.

The court begins with the balance-of-equities and the public-interest factors, which merge when, as in this case, the government is a party. *See Nken v. Holder*, 556 U.S. 418, 435 (2009). Those factors weigh heavily against injunctive relief. The relief requested, if granted, would have the effect of negating for the foreseeable future a portion of the orders entered in *American Academy of Pediatrics v. Food and Drug Administration* ("*AAP*"). In that action, a coalition of public health groups and doctors convinced the district court that the Food and Drug Administration's ("FDA") multi-year delay in enforcing the statutory premarket review requirement for products newly deemed under the Final Deeming Rule violated the Family Smoking Prevention and Tobacco Control Act ("TCA") and the APA. *See AAP*, 379 F. Supp. 3d 461 (D. Md. 2019). The *AAP* court ultimately entered an order vacating the FDA's announced

delay in accepting premarket applications for newly deemed products, including cigar and pipe tobacco products. *Id.* at 498. It also compelled the agency to require manufacturers of all newly deemed products to file premarket applications by September 9, 2020. *See AAP*, 399 F. Supp. 3d 479, 487 (D. Md. 2019).[1] The injunctive relief requested here would upset the *AAP* court's judgment without justification. It would, in the short term, exempt from the *AAP* court's order all newly deemed cigar and pipe tobacco products. Such collateral relief from another court's order is generally unwarranted. *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"). Abstaining from such collateral relief is particularly apt in this case, where Plaintiff had ample opportunity to participate in the *AAP* litigation but simply delayed in doing so. As this court explained in denying Plaintiffs' request for declaratory relief as to Count X of their Amended Complaint, "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* Order, ECF No. 158, at 4–5. Plaintiffs simply acted too late. It would be inequitable for this court to undo, even temporarily, the hard-fought victory achieved by the plaintiffs in *AAP*. The *AAP* plaintiffs' interests, avoiding an unnecessary conflict with the *AAP* court's decision, and the public's interest in enforcing the *AAP* court's remedial order, all counsel strongly against injunctive relief pending appeal.

Admittedly, this court entered judgment in favor of Plaintiffs on Count XIV and fashioned relief that enjoins the FDA from enforcing the substantial equivalence deadline as to manufacturers of premium cigars (a newly deemed product) while the subject matter of that claim is considered

[1] The *AAP* court originally had set the deadline as May 12, 2020, but extended it to September 9, 2020, at the FDA's request to account for the compliance challenges caused by the COVID-19 pandemic. *See* Mem. Op. at 7.

on remand. Mem. Op. at 35–37. In granting that relief, the court acknowledged the "tension" created with the relief afforded in *AAP*, but ultimately saw no irreconcilable conflict because "the *AAP* court did not have before it the specific issues presented here, nor does anything in its order foreclose another court from remedying errors made by the FDA in promulgating the Final Deeming Rule." *Id.* at 37. Similar relief is not warranted in the present posture, however, where the court already has ruled against Plaintiff on the counts that it claims raise serious legal questions—Counts XI and XIII. The D.C. Circuit is the proper forum to issue any additional relief that might have the effect of intruding on the *AAP* court's judgment and orders, not this court.

III.

Plaintiff also falls short of showing irreparable harm. Plaintiff primarily relies on the costs associated with complying with the upcoming premarket review deadline as the harm its members will suffer in the absence of injunctive relief. Such costs, Plaintiff argues, will be magnified because the FDA has failed to issue guidance on the contents of the substantial equivalence reports that cigar and pipe tobacco manufacturers will be required to file. *See* Pl.'s Mem. in Support of Pl.'s Mot., ECF No. 216, at 10–11 [hereinafter Pl.'s Mem.]. But, as Defendants point out, the costs that Plaintiff's members will incur in filing reports by September 9, 2020, are costs they will incur at some point in the future. Defs.' Opp'n to Pl.'s Mot., ECF No. 222, at 7. Exercising its authority under the TCA, the FDA "deemed" all cigar and pipe tobacco products; as a result, those goods are now subject to the requirements of the TCA, including securing premarket authorization. No relief that the D.C. Circuit could fashion on the appealed claims could entirely negate that eventuality.[2] Thus, cigar and pipe tobacco product manufacturers, if not now, eventually will have

[2] Plaintiffs advanced no claim before this court asserting that the FDA acted unlawfully in the first instance by deeming cigar and pipe tobacco products. If Plaintiffs had prevailed on such a claim, vacatur of the Final Deeming Rule as to those products would have relieved Plaintiffs of the premarket authorization requirement. But such relief is not available based on the more circumscribed claims Plaintiffs seek to have reviewed on appeal.

to file for premarket approval with the FDA. How much additional cost cigar and pipe tobacco manufacturers face from the impending deadline is difficult to quantify—Plaintiff offers no evidence to this effect—but those manufacturers cannot escape incurring any costs altogether.

Plaintiff relies heavily on this court's grant of an injunction pending appeal in an earlier phase of this litigation in *Cigar I*. But that situation was different. The primary harm there, if the court had not issued an injunction, was the infringement of Plaintiffs' First Amendment rights. *See* 317 F. Supp. 3d at 562. There is no constitutional right at stake here. The court in *Cigar I* did go on to consider, "[i]n addition to constitutional injury," the financial costs Plaintiffs would incur absent injunctive relief, but the cost of compliance there would have been fully avoidable if Plaintiffs prevailed on appeal (as they eventually did). *Id.* at 563. Here, by contrast, as discussed, Plaintiff cannot avoid compliance costs even if they were to succeed on appeal; some portion of those costs will be incurred in the future.

Plaintiff also cite as irreparable harm the dangers that the COVID-19 pandemic presents to its members' employees who will have to work to meet the September 9 deadline. *See* Pl.'s Mem. at 11. The court understands that concern. It is real and legitimate. But the FDA, with the consent of the *AAP* court, already extended the original deadline of May 12, 2020, by four months to account for the difficulties presented by the pandemic. *See* n.1, *supra.* Those challenges may be no less significant today, but Plaintiff cannot claim that the deadline has snuck up on them with no opportunity to adjust to the present realities.

IV.

As for the likelihood-of-success factor, a party seeking an injunction pending appeal need not convince the court that it erred to obtain relief; it is sufficient to show that the case presents "serious legal questions on appeal." *See Cigar I*, 317 F. Supp. 3d at 561. The court need not,

however, pass on the "seriousness" of the Plaintiff's claims with respect to Counts XI and XIII—the only two counts Plaintiff's motion addresses on the merits. For even if serious, the other three factors to do not "strongly favor" injunctive relief. *Id.* (citing *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)).

V.

Finally, Plaintiff asks for equitable relief under 5 U.S.C. § 705. That statute allows courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status and rights pending conclusion of the review proceedings." Courts in this District have treated the showing required for interim relief under § 705 as co-extensive with the four traditional factors for injunctive relief. *See Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 30 (D.D.C. 2012) (collecting cases). Plaintiff disputes that approach, suggesting that relief under § 705 presents a lower bar. *See* Pl.'s Mem. at 26 n.9. Whatever the merits of that contention, relief under § 705, at a minimum, requires a showing of "irreparable injury." 5 U.S.C. § 705 (providing that a court may issue relief "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury"). Plaintiff has not made that showing here.

VI.

For the foregoing reasons, Plaintiff Cigar Association of America's Motion for a Stay, ECF No. 216, is hereby denied.

Dated: September 2, 2020

Amit P. Mehta
United States District Judge