

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 6:20-cv-00176

**DEFENDANTS' OPPOSITION TO MOTION TO EXTEND POSTPONEMENT
OF RULE'S EFFECTIVE DATE**

Defendants oppose Plaintiffs' motion to further postpone the effective date of the Food and Drug Administration's ("FDA") new cigarette health warnings rule, *see* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15,638 (Mar. 18, 2020) ("the Rule"). The Rule's effective date—originally slated for June 18, 2021, *see id.* at 15,638—has already been postponed by 120 days to October 16, 2021. *See* Order at 2, ECF No. 33 (May 8, 2020). The Court ordered that postponement following a joint motion in which the parties emphasized "the extraordinary disruptions caused by the COVID-19 pandemic" and the desire "to facilitate the efficient briefing and resolution of this case[.]" Joint Mot. for Entry of Stipulated Order at 1, ECF No. 30 ("Joint Mot."). Since that filing, the parties have briefed all of the motions contemplated in their joint motion, including Plaintiffs' motion for preliminary injunction, *see* Pls.' Mot. for Summ. J. & Prelim Inj. at 59, ECF No. 34 ("Pls.' MSJ Br.") (requesting that the Court "preliminarily enjoin the Rule and postpone its effective date").¹

¹ The parties have also briefed (and argued) Defendants' Motion to Dismiss, ECF No. 36. Because Plaintiff Neocom lacks standing, which renders venue in this district improper, the Court should dismiss—or, in the alternative, transfer—this case. *See id.* at 14. Accordingly, the Court need only consider the arguments in this opposition if it denies, or has not yet resolved, the Motion to Dismiss.

Plaintiffs' motion seeks an additional 90-day postponement of the Rule's effective date, until January 14, 2022. *See* Pls.' Mot. to Extend Postponement of Rule's Effective Date at 5, ECF No. 76 ("Pls.' Mot."). To support that request, Plaintiffs rely exclusively on materials they already submitted in support of their motion for preliminary injunction. *See id.* at 3-5 (citing the Huckabee, Reed, and Wall declarations, ECF Nos. 34-5, 34-6, 34-7). But as Defendants explained in opposing that motion, Plaintiffs have not set forth evidence sufficient to meet their "burden to demonstrate entitlement to [an] 'extraordinary remedy never awarded as of right[.]'" Defs.' Combined Cross-Mot. for Summ. J. & Opp. to Pls.' Mot. at 73, ECF No. 37 (citation omitted); *see also id.* at 73-75.

The same analysis applies with force here. In particular, because the Court can now conclude that Plaintiffs will not succeed on the merits by consulting the same briefs that address Plaintiffs' motions for summary judgment and for a preliminary injunction, there is no basis for further preliminary relief. Nor is there a basis for finding imminent irreparable harm. Plaintiffs' primary arguments about irreparable harm concern injuries they will allegedly suffer only once they have to introduce cigarette packages and advertisements that comply with the Rule—*i.e.*, not until the Rule is in effect. *See* Pls.' MSJ Br. 59-60 (alleging First Amendment injuries and loss of future business). And none of the financial harms they allege approach the level of "threaten[ing] the very existence of some of [Plaintiffs'] businesses," unlike other injuries the Fifth Circuit has found warrant a stay of agency action. *Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016).

Moreover, Plaintiffs' arguments about allegedly "imminent compliance costs," Pls.' Mot. at 3, do not support their assertion that the rushed relief of an effective-date extension must issue by December 2020. Plaintiffs place considerable weight on the costs of "purchas[ing] additional blank cylinder bases and tools," *id.* at 4, but those costs do not appear to be imminent until January 2021—*i.e.*, ten months after the Rule was published on March 18, 2020. *See* Huckabee Decl. ¶ 11, ECF No. 34-5 ("[T]he work to engrave the cylinders will take several months and must begin within ten months after the Rule is published[.]"); Reed Decl. ¶ 10, ECF No. 34-6 ("[T]he work to engrave the cylinders will take at least five months and must begin within ten months after the Rule is published."). And although one declarant for one brand (Liggett) has stated that "engraving [of the cylinders] would

need to begin by December 2020,” Wall Decl. ¶ 19, ECF No. 34-7, that assertion appears to be based on simply taking the longer of two estimates for how long the engraving process will take. *Compare id.* (“Under ideal circumstances, the engraving process would take approximately five *or* six months, meaning engraving would need to begin by December 2020.” (emphasis added)), *with* Reed Decl. ¶ 10 (suggesting engraving will take “at least five months” and therefore must begin in January 2021). Absent any evidence that one estimate is more likely than the other, Plaintiffs have not carried their burden to make “a clear showing” that irreparable harm is imminent before this Court can reach a decision on the merits. *See Elite Rodeo Ass’n v. Prof’l Rodeo Cowboys Ass’n, Inc.*, 159 F. Supp. 3d 738, 748 (N.D. Tex. 2016); *see also Parks v. Dunlop*, 517 F.2d 785, 787 (5th Cir. 1975) (noting that “the central purpose of a preliminary injunction . . . is to prevent irreparable harm . . . before the merits are fully determined”).²

If, however, the Court disagrees with the foregoing arguments and further extends the Rule’s effective date over Defendants’ objection, then Defendants agree with Plaintiffs that the statutory deadlines “tied to the issuance of the Rule” should move in conjunction with the Rule’s effective date. Pls.’ Mot. at 5 n.1. In other words, if (and only if) the Court extends the Rule’s effective date by 90 days, it should also extend the statutory deadlines tied to the issuance of the Rule by 90 days as well.³

² With respect to the work that allegedly needs to be done “before . . . the engraving of the printing cylinders,” Pls.’ Mot. at 3, Plaintiff have introduced no evidence as to how much—if any—of that work remains outstanding.

³ Those deadlines are identified in the parties’ prior joint motion, *see* Joint Mot. at 4 n.1, and reiterated in Plaintiffs’ instant motion, *see* Pls.’ Mot. at 5 & n.1. Separate and apart from those statutory deadlines, the Rule addresses the timeframe for cigarette manufacturers to submit compliance plans. But rather than establish a fixed deadline for those plans, FDA “strongly encourage[d] entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within five months after the publication of this final rule.” 85 Fed. Reg. at 15,695. Because there is just an agency *recommendation* regarding compliance plans, there is no statutory or regulatory *deadline* for this Court to potentially alter. FDA can consider, in its discretion, whether its own non-binding recommendations should be modified. Accordingly, any relief this Court orders need not and should not address the submission of compliance plans. *See* Joint Mot. at 4 n.1 (directing a request to the Court regarding “any obligation to comply with the[] additional [statutory] requirements,” but separately noting that the timeframe for “manufacturers [to] submit compliance plans” would be the subject of an understanding between the parties).

For these reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to extend the postponement of the Rule's effective date.

Dated: November 25, 2020

Respectfully submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General

STEPHEN J. COX
United States Attorney

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Michael H. Baer
MICHAEL H. BAER (New York 5384300)
STEPHEN M. PEZZI (Virginia 84311)
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8576
Fax: (202) 616-8470
Email: stephen.pezzi@usdoj.gov