

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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

**MEMORANDUM OPINION**

Pursuant to Federal Rule of Civil Procedure 62(c) and 5 U.S.C. § 705, Plaintiffs ask for an injunction or stay pending their appeal of a portion of the court’s May 15, 2018 Memorandum Opinion and Order, which granted in part and denied in part Plaintiffs’ Motion for Partial Summary Judgment and denied as moot Plaintiffs’ Motion for Preliminary Injunction. Specifically, Plaintiffs seek “an injunction against the enforcement of the [Food and Drug Administration’s (“FDA”)] cigar and pipe tobacco warnings requirements set forth at 21 C.F.R. §§ 1143.3 and 1143.5” or “a postponement of the August 10, 2018 effective date of those requirements,” while their appeal is pending and for 60 days after the resolution of that appeal. *See* Pls.’ Mot. for Stay or Inj. Pending Appeal, ECF No. 95 [hereinafter Pls.’ Mot.], at 1. Alternatively, Plaintiffs move to postpone the effective date of the cigar warnings requirements, *see* 21 C.F.R. § 1143.5, until 60 days after the court resolves Count V of the Complaint, which challenges the FDA’s decision to subject premium cigars to the same regulatory regime as other cigar products, *id.*; *see* Compl., ECF No. 1, ¶¶ 125–33.

The court grants Plaintiffs’ Motion for an Injunction Pending Appeal. The issues appealed by Plaintiffs present “serious legal questions” as to the constitutionality of FDA’s warnings regime, a conclusion only reinforced by the Supreme Court’s recent decision in *National Institute of Family and Life Advocates v. Becerra*, No. 16-1140, 2018 WL 3116336 (U.S. June 26, 2018). Additionally, Plaintiffs likely will suffer irreparable harm absent injunctive relief: they will have to communicate purely factual government speech in a form and size to which they object; will have their own commercial speech diminished; and will have to incur millions of dollars in compliance costs, which they will not be able to recover if the warnings regime is determined to be unconstitutional. Finally, both the balance of equities and the public interest favor an injunction pending appeal.

In the end, this court believes that Plaintiffs are entitled to a full hearing before an appellate court without the specter of a warnings regime going into effect that might ultimately be found to run afoul of the First Amendment. Accordingly, the court enjoins Defendants from enforcing the new warnings requirements for cigars and pipe tobacco set forth in 21 C.F.R. §§ 1143.3 and 1143.5 until final disposition of Plaintiffs’ appeal.<sup>1</sup>

I.

The court starts with a brief overview of the relevant history of this case.<sup>2</sup> On May 10, 2016, the FDA published a final rule—the “Deeming Rule”—subjecting cigars, pipe tobacco, and other products to statutory and regulatory requirements comparable to those already imposed on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. *See* 81 Fed. Reg.

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<sup>1</sup> Because the court finds that Plaintiffs are entitled to an injunction pending appeal pursuant to Rule 62(c), the court does not address Plaintiffs’ request for relief under 5 U.S.C. § 705.

<sup>2</sup> For a more detailed factual and procedural background, the court directs the reader to its May 15, 2018 Memorandum Opinion and Order. *See* ECF No. 94.

28,974 (May 10, 2016). As relevant here, the Deeming Rule imposed comprehensive warning statement requirements for pipe tobacco and cigar products. Effective August 10, 2018, cigar product packaging and advertisements must display one of six health warning statements regarding the health risks associated with cigar and nicotine use. *See* 21 C.F.R. § 1143.5(a)(1); *see also id.* § 1143.13. On cigar product packages, each warning statement must occupy “at least 30 percent of each of the principal display panels.” *Id.* § 1143.5(a)(2). On cigar product advertisements, each warning statement must occupy “at least 20 percent of the area of the advertisement.” *Id.* § 1143.5(b). The Deeming Rule imposed similar warnings requirements on pipe tobacco products.<sup>3</sup>

Plaintiffs filed a nine-count complaint in July 2016, challenging aspects of the Deeming Rule, including the warning requirements, as violative of the Tobacco Control Act (“TCA”), the Administrative Procedure Act (“APA”), and the U.S. Constitution. *See generally* Compl. Following a series of extensions requested by the parties in order to allow the newly installed FDA administration time to evaluate its approach to the Deeming Rule, *see* Mem. Op. & Order, ECF No. 94 [hereinafter Mem. Op.], at 15–16, the parties jointly agreed to defer resolution of certain of Plaintiffs’ challenges, namely, Counts I, IV, and V of the Complaint, *see* Joint Status Report, ECF No. 53. During this same period, the FDA announced a “new comprehensive plan” for regulating tobacco products and nicotine, pursuant to which the FDA postponed implementation of some provisions of the Deeming Rule, but not others including the warnings requirements. Mem. Op. at 13. As part of the new plan, the FDA announced that it would issue an Advanced Notice of Proposed Rulemaking (“ANPRM”), inviting the public to submit studies and information

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<sup>3</sup> Effective August 10, 2018, all pipe tobacco packaging and advertisements must display a warning about nicotine addictiveness. *See* 21 C.F.R. § 1143.3(a)(1). On pipe tobacco packages, this warning must occupy at least 30 percent of two principal display panels. *Id.* § 1143.3(a)(2). On pipe tobacco advertisements, the warning must occupy at least 20 percent of the area of the advertisement. *Id.* § 1143.3(b)(2).

regarding the health warnings requirements for a higher-end cigar product, known as “premium cigars,” and requesting public comment on the propriety of “additional or alternative warning statements” for such products. *See Regulation of Premium Cigars*, 83 Fed. Reg. 12,901, 12,904 (Mar. 26, 2018). Premium cigars typically are hand-rolled, are made with a higher-grade tobacco, or are more expensive than other cigars. *See* Mem. Op. at 4 (citing Defs.’ Cross-Mot. for Partial Summ. J. & Mem. in Supp., ECF No. 74, at 8).

Plaintiffs moved for partial summary judgment on October 3, 2017. *See* Pls.’ Mot. for Partial Summ. J., ECF No. 62. In pertinent part, Plaintiffs pressed their claims in Counts VI and VII of their Complaint, which alleged that the Deeming Rule’s warning statement requirements violate the TCA, APA, and the First Amendment. Plaintiffs concurrently sought a preliminary injunction restraining the FDA from implementing or enforcing the warnings requirements. Pls.’ Mot. for Prelim. Inj., ECF No. 61. The parties consented to consolidating the motion for preliminary relief with briefing on the merits. *See* Order, ECF No. 57 (dated Sept. 19, 2017); *see also* Fed. R. Civ. P. 65(a)(2).

The court granted in part and denied in part Plaintiffs’ motion for partial summary judgment and denied Plaintiffs’ motion for a preliminary injunction as moot. *See* Mem. Op. at 70. As relevant here, the court rejected Plaintiffs’ argument that the Deeming Rule’s health warnings requirements violate the TCA or APA. *See id.* at 18–26. Additionally, as to Plaintiffs’ First Amendment challenge, the court assessed the warnings mandate under the constitutional test articulated in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). Finding that the warnings required disclosure of “purely factual and uncontroversial information about the good or service being offered,” Mem. Op. at 29 (quoting *Am. Meat Inst. v. U.S. Dep’t of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014)), the court held that “[b]ecause the warning

statements are . . . aimed at informing the public about the risks of cigar and pipe tobacco use and at correcting the public's misperceptions about such products' use, and because the Rule does not impose these requirements in an 'unjustified or unduly burdensome' manner, the Rule is constitutional under *Zauderer*," Mem. Op. at 43–44.

Plaintiffs filed the instant Motion on June 8, 2018, *see* Pls.' Mot., which Defendants oppose, *see* Defs.' Mem. in Opp'n to Pls.' Mot., ECF No. 99 [hereinafter Defs.' Opp'n]. Some three weeks later, on June 27, 2018, pursuant to Rule 54(b) and with the parties' consent, the court entered final judgment in favor of Defendants on Counts VI and VII of the Complaint. Order, ECF No. 101. Plaintiffs then noticed their appeal to the D.C. Circuit as to those claims. Notice of Appeal, ECF No. 102.

## II.

Federal Rule of Civil Procedure 62(c) authorizes a district court to issue an injunction pending appeal. Fed. R. Civ. P. 62(c). A motion brought under Rule 62(c) is subject to the same four criteria as a motion for preliminary injunction. *See Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 842–43 (D.C. Cir. 1977). Thus, to obtain an injunction pending appeal, the moving party "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *accord Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curiam) (citing *Holiday Tours*, 559 F.2d at 843–44).

Courts in this Circuit traditionally have analyzed these four factors on a "sliding scale," whereby "a strong showing on one factor could make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). When considering a motion under Rule

62(c), the “sliding scale” framework allows a movant to remedy a lesser showing of likelihood of success on the merits with a strong showing as to the other three factors, provided that the issue on appeal presents a “serious legal question” on the merits. *Holiday Tours*, 559 F.2d at 844; *see also Al-Ananzi v. Bush*, 370 F. Supp. 2d 188, 193 n.5 (D.D.C. 2005) (noting that when evaluating a request for an injunction pending appeal, “courts often recast the likelihood of success factor as requiring only that the movant demonstrate a serious legal question on appeal where the balance of harms strongly favors a stay”).

Whether the sliding scale framework survives the Supreme Court’s decision in *Winter v. Natural Resources Defense Council* has not been resolved by the Circuit. *See Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014). Thus, “it remains an open question whether the ‘likelihood of success’ factor is an ‘independent, free-standing requirement,’ or whether, in cases where the three other factors strongly favor issuing an injunction, a plaintiff need only raise a ‘serious legal question’ on the merits.” *Id.* (quoting *Sherley*, 644 F.3d at 393, 398). While acknowledging this uncertainty, the district judges in this Circuit continue to adhere to binding precedent and apply the sliding scale approach to determine whether a movant is entitled to an injunction pending resolution of its appeal. *E.g., Akiachak Native Cmty. v. Jewell*, 995 F. Supp. 2d 7, 12–13 (D.D.C. 2014); *see also Dunlap v. Presidential Advisory Comm’n on Election Integrity*, No. 17-2361, 2018 WL 3150217, at \*25–26 (D.D.C. June 27, 2018) (observing that “a ‘serious legal question’ could help tip the scales . . . when the likelihood of success on appeal is low”). This court must do the same. Thus, the court may grant Plaintiffs’ motion and issue an injunction pending appeal if a “serious legal question is presented, . . . little if any harm will befall other interested persons or the

public, and . . . denial of the order would inflict irreparable injury on [Plaintiffs].” *Holiday Tours*, 559 F.2d at 844; *accord Akiachak Native Cmty.*, 995 F. Supp. 2d at 12–13.<sup>4</sup>

### III.

#### A. Likelihood of Success on the Merits

The court begins with Plaintiffs’ likelihood of success on the merits of their appeal. As to this factor, Defendants assert that, because the court already has ruled against Plaintiffs after a full hearing, Plaintiffs cannot establish that they are likely to succeed on the merits. *See* Defs.’ Opp’n at 2–3. Defendants’ contention is premised on their view that the Supreme Court’s decision in *Winter* supplants D.C. Circuit authority allowing a district court to “grant a stay even though its own approach may be contrary to [the] movant’s views on the merits,” so long as the other three factors strongly favor interim relief and the case presents serious legal questions on appeal. *See Holiday Tours*, 559 F.2d at 843–44. But, while some judges of the D.C. Circuit have questioned the continuing validity of the sliding-scale approach after *Winter*, *see, e.g., Davis v. Pension Benefit Guaranty Corp.*, 571 F.3d 1288, 1295–96 (D.C. Cir. 2009) (Kavanaugh, J., concurring), the Circuit has yet to disavow it, *cf. John Doe Co. v. Consumer Financial Protection Bureau*, 849 F.3d 1129, 1131–32 (D.C. Cir. 2017) (citing *Holiday Tours*, 559 F.2d at 844). Therefore, as already discussed, this court remains bound by the standard announced in *Holiday Tours*. Accordingly, the fact that the court does not share Plaintiffs’ conviction that it erred is not fatal to their request for an injunction pending appeal.

To that end, the court agrees with Plaintiffs that the issues raised as part of their challenge to the Deeming Rule’s warnings requirements present “serious legal questions going to the merits,

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<sup>4</sup> The court notes the near impossible position a losing party would find itself in if it were required to convince a judge who had just ruled against it that the party is likely to succeed on appeal. In such circumstances, a court would need to determine that it had erred in its ruling, “an acknowledgement one would expect few courts to make,” rendering a Rule 62(c) injunction extremely rare. *See Loving v. IRS*, 920 F. Supp. 2d 108, 110 (D.D.C. 2013).

so serious, substantial, difficult as to make them a fair ground of litigation and thus for more deliberative investigation.” *Population Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986) (quoting *Holiday Tours*, 559 F.2d at 844); *see also John Doe Co.*, 849 F.3d at 1132 (stating as to the first prong that the movant must show that “there is potentially persuasive authority for its legal position”). Plaintiffs’ First Amendment challenge to the warnings requirements involves a host of complex, purely legal questions, including but not limited to: whether Defendants’ asserted governmental interest in imposing the health warnings regime is a substantial one; the precise burden the government bears under *Zauderer* to compel purely factual and uncontroversial government speech; and whether a disclosure of the size and appearance mandated by the warnings requirements is so “unduly burdensome” as to chill protected speech. These are difficult legal questions, and the D.C. Circuit might well disagree with this court’s resolution of them.

The Supreme Court’s recent decision in *National Institute of Family and Life Advocates v. Becerra*, No. 16-1140, 2018 WL 3116336 (U.S. June 26, 2018), only adds to the substantiality of the issues Plaintiffs intend to raise on appeal. In *Becerra*, the Court addressed a California statute requiring unlicensed clinics serving pregnant women to provide a government-drafted notice on site and in all advertising materials notifying women that the clinics were not licensed by California to provide medical services. *Becerra*, 2018 WL 3116336, at \*6. The Court held that, even under *Zauderer*’s more relaxed standard, the compelled disclosures were unjustified and unduly burdensome and that the unlicensed clinics were likely to succeed on the merits of their claim that the California notice requirement violates the First Amendment. *Id.* at \*14–16. In Plaintiffs’ view, “[t]his court’s analysis likely would not survive an application of *Becerra*.” Pls.’ Reply in Supp. of Mot. for Stay, ECF No. 104 [hereinafter Pls.’ Reply], at 6. In particular, they emphasize the Supreme Court’s admonishment that a compelled disclosure be “no broader than



reasonably necessary” in order to survive scrutiny under *Zauderer*, a standard they contend is more demanding than that articulated by the D.C. Circuit in the cases that this court relied on in its Memorandum Opinion. Pls.’ Reply at 3–5 (quoting *Becerra*, 2018 WL 3116336, at \*14). This court does not concur that *Becerra* requires an outcome different than the one the court reached—*Becerra* differs from this case in multiple, material ways—but that disagreement does not diminish the merits of Plaintiffs’ motion. *Becerra* makes clear that Plaintiffs’ appeal raises serious legal questions.

In light of the complexity of the issues raised by Plaintiffs on appeal and the Supreme Court’s recent decision in *Becerra*, the court finds that the instant case presents serious legal questions on the merits. Accordingly, if the remaining three factors weigh heavily in favor of Plaintiffs, an injunction pending appeal is warranted.

#### B. Irreparable Harm

Moving on to the second factor, Plaintiffs have made a showing of irreparable harm. To meet the “high standard for irreparable injury,” the moving party must demonstrate an injury that is “both certain and great” and must also “show ‘[t]he injury complained of is of such *imminence* that there is a ‘clear and present’ need for equitable relief to prevent irreparable harm.” *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam)).

If denied an injunction, Plaintiffs will incur an injury that is “certain” and “imminent.” “The loss of First Amendment freedoms, for even minimal periods of time . . . constitute[s] irreparable injury.” *Id.* at 301 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). Although it is true that the mere incantation of the First Amendment is not sufficient to establish irreparable harm, Plaintiffs have done more than “merely allege a violation of freedom of expression”; they

have shown that the impending compliance date “threaten[s] or in fact . . . impair[s]” their First Amendment interests “at the time relief is sought.” *Id.* (quoting *Nat’l Treasury Emps. Union v. United States*, 927 F.2d 1253, 1254–55 (D.C. Cir. 1991)). By August 10, 2018, Plaintiffs must comply with the health warnings requirements for cigars and pipe tobacco set forth in 21 C.F.R. §§ 1143.3 and 1143.5. Satisfying this mandate will require Plaintiffs to communicate a government message for which they claim there is no substantial government interest and is in a form and size that they assert is unduly burdensome and “crowds out” lawful commercial expression. In this instance, the First Amendment impairment constitutes irreparable harm.

In addition to constitutional injury, Plaintiffs here will incur actual financial harm, in the form of “millions of dollars in designing and creating new, conforming packaging.” *Mem. Op.* at 46. If the warnings regime is struck down, these expenditures would be unrecoverable, leaving Plaintiffs with no remedy to restore themselves “to the status quo ante.” *See Mann v. Wash. Metro. Transit Auth.*, 185 F. Supp. 3d 189, 195 (D.D.C. 2016). Such irrecoverable financial loss is “great,” *N. Air Cargo v. USPS*, 756 F. Supp. 2d 116, 125 n.6 (D.D.C. 2010), in this case, for purposes of establishing irreparable harm.

Accordingly, Plaintiffs have met the high bar of demonstrating that they will suffer irreparable harm in the absence of injunctive relief pending appeal.

### C. Balance of Equities

The balance of equities also weighs in favor of Plaintiffs. The court already has made its view of the equities clear. *See Mem. Op.* at 46–49. The court need not repeat itself here, save to reiterate that the FDA’s insistence that the cigar industry, as a whole, meet the August 10, 2018, effective date, while the agency seeks additional information that bears on the need for health warnings on premium cigars is “a grossly unfair exercise of agency authority.” *Id.* at 46.

In contrast to the irreparable harm Plaintiffs will incur without an injunction, there is little indication that an injunction pending appeal will result in substantial harm to Defendants. Defendants do not contend otherwise. *See generally* Defs.’ Opp’n. Accordingly, Plaintiffs’ interest in staying the impending compliance date outweighs the minimal burden placed on Defendants to delay its enforcement.

#### D. Public Interest


Finally, the public interest favors granting injunctive relief pending resolution of the appeal. The “strong public interest in the exercise of free speech rights,” *Pursuing America’s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016), will be served by “ensuring that [P]laintiffs’ First Amendment rights are not infringed before the constitutionality of the regulation has been definitively determined,” *Stewart v. District of Columbia Armory Bd.*, 789 F. Supp. 402, 406 (D.D.C. 1992). Although Defendants rightly observe that the public has an interest in ensuring that the FDA can exercise its authority and scientific expertise to inform the public about the health risks posed by cigar and pipe tobacco products, Defendants offer no persuasive argument that there is an immediate public interest in enforcing the warnings requirements on August 10, 2018, rather than after a full hearing on appeal. That there is no immediate public interest is reinforced by the fact that Defendants are considering rulemaking that might alter the warnings requirements as to premium cigars, a key covered product. In sum, the court concludes that the public’s interest in preserving constitutional protections is best served by granting Plaintiffs’ request for injunctive relief.

#### IV.

Because Plaintiffs’ appeal presents “serious legal questions” on the merits, and because the likelihood of irreparable harm, the balance of equities, and the public interest all strongly favor

interim relief, the court exercises its discretion to grant Plaintiffs' Motion for an Injunction Pending Appeal. Defendants are hereby enjoined from enforcing the health warnings requirements for cigars and pipe tobacco set forth in 21 C.F.R. §§ 1143.3 and 1143.5 until 60 days after final disposition of Plaintiffs' appeal. A separate Order accompanies this Memorandum Opinion.

Dated: July 5, 2018



Amit P. Mehta  
United States District Judge