UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY,	)	
LORILLARD TOBACCO COMPANY,	)	
COMMONWEALTH BRANDS, INC.,	)	
LIGGETT GROUP LLC,	)	
and	)	
SANTA FE NATURAL TOBACCO COMPANY, INC.,	)	
Plaintiffs,	)	
v.	)	**Civil Case No. 11-1482 (RJL)**
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration,	)	
and	)	
KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,	)	
Defendants.	)	

MEMORANDUM OPINION
November 7, 2011 [Dkt. #11]

Plaintiffs in this case ("plaintiffs") are five tobacco companies, which include the second-, third-, and fourth-largest tobacco manufacturers and the fifth-largest cigarette manufacturer in the United States. Complaint ("Compl."), Aug. 16, 2011, ¶¶ 8-12 [Dkt.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

#1]. In June 2011, defendant United States Food and Drug Administration ("FDA") published a Final Rule requiring (among other things) the display of nine new textual warnings – along with certain graphic images[1] such as diseased lungs and a cadaver bearing chest staples on an autopsy table – on the top 50% of the front and back panels of every cigarette package manufactured and distributed in the United States on or after September 22, 2012. *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("the Rule"); *see also* Pls.' Mot. for Preliminary Injunction ("Mot. for PI"), Aug. 19, 2011, at 1-3 [Dkt. #11]. Alleging that the Rule violates the First Amendment and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553(b)(3), 705, 706(2)(A), *see* Compl. ¶¶ 5-6, plaintiffs now seek a preliminary injunction against the FDA, the Secretary of the U.S. Department of Health and Human Services ("the Secretary"), and the Commissioner of the FDA ("the Commissioner" and together, "defendants" or "the Government"), to enjoin enforcement of the Rule until fifteen months *after* resolution of plaintiffs' claims on the merits.[2] Mot. for PI at 1, 5-6. As such, plaintiffs raise for the first time in our Circuit the question of whether the FDA's new and mandatory graphic images, when combined with certain

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[1] The FDA conveniently refers to these graphic images as "graphic warnings." While characterizing the mandatory textual statements as "warnings" seems to be a fair and accurate description, characterizing these graphic images as "warnings" strikes me as inaccurate and unfair. At first blush, they appear to be more about shocking and repelling than warning. Accordingly, I will refer to them simply as graphic images, and set this self-serving "warning" label aside for closer analysis on another day.

[2] Plaintiffs filed a Motion for Summary Judgment [Dkt. #10] on the same day they filed their Motion for Preliminary Injunction [Dkt. #11]. The Motion for Summary Judgment, however, is not before the Court today.

textual warnings on cigarette packaging, are unconstitutional under the First Amendment. Upon review of the pleadings, the parties' supplemental pleadings, oral argument, the entire record, and the applicable law, the Court concludes that plaintiffs have demonstrated a substantial likelihood that they will prevail on the merits of their position that these mandatory graphic images unconstitutionally compel speech, and that they will suffer irreparable harm absent injunctive relief pending a judicial review of the constitutionality of the FDA's Rule. For that and the other reasons stated herein, I hereby GRANT plaintiffs' Motion for Preliminary Injunction.[3]

BACKGROUND

I. Statutory and Regulatory History

A. The Act

The Family Smoking Prevention and Tobacco Control Act ("Act" or "the Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), which President Obama signed into law on June 22, 2009, gives the FDA the authority to regulate the manufacture and sale of tobacco products, including cigarettes.[4] Defs.' Opp'n at 1. Pursuant to that authority,

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[3] Plaintiffs bring both First Amendment and APA claims. At the September 21, 2011 hearing, however, all parties agreed that if plaintiffs prevailed on their First Amendment claim, resolution of the APA claim would be superfluous. *See* Tr. 68:10-19 (Government), 71:17-22 (plaintiffs). Because plaintiffs prevail on their First Amendment claim, an analysis of the APA claim is unnecessary.

[4] Plaintiffs note that preceding the Act, and indeed, "[f]or more than 45 years, cigarettes sold in the United States have been accompanied by various Surgeon General Warnings," and that "Plaintiffs have never brought a legal challenge to any of them." Compl. ¶ 1.

Congress – following the lead of the Canadian government[5] – directed the Secretary to "issue regulations that require color graphics depicting the negative health consequences of smoking."[6] *See* Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333(d)); Compl. ¶ 31; Defs.' Opp'n at 1. In addition, Congress required all cigarette packages manufactured, packaged, sold, distributed, or imported for sale or distribution within the United States to bear one of the following nine textual warnings:

> "**WARNING:** Cigarettes are addictive.
>
> **WARNING:** Tobacco smoke can harm your children.
>
> **WARNING:** Cigarettes cause fatal lung disease.
>
> **WARNING:** Cigarettes cause cancer.
>
> **WARNING:** Cigarettes cause strokes and heart disease.
>
> **WARNING:** Smoking during pregnancy can harm your baby.
>
> **WARNING:** Smoking can kill you.
>
> **WARNING:** Tobacco smoke causes fatal lung disease in nonsmokers.
>
> **WARNING:** Quitting smoking now greatly reduces serious risks to your health."[7] Act § 201(a) (amending 15 U.S.C. § 1333(a)(1)).

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[5] It is no secret that the Congress was greatly influenced in the drafting and passage of this aspect of the legislation by the example of our northerly neighbors. *See, e.g.*, Defs.' Opp'n at 2, 9, 11-13, 18-20.

[6] The statute also vests a certain amount of discretion in the Secretary, who "may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333(d)).

[7] The Act also imposes a number of related labeling requirements which require that cigarette packages display specific information about, for example, the tobacco

Congress required that these new textual warnings and graphic images occupy the top 50% of the front and back panels of all cigarette packages, Act § 201(a) (amending 15 U.S.C. § 1333(a)(2)), and the top 20% of all printed cigarette advertising, *id.* (amending 15 U.S.C. § 1333(b)(2)). It gave the FDA "24 months after the date of enactment" of the Act to issue regulations implementing the requirements of Section 201. Act § 201(a) (amending 15 U.S.C. § 1333(d)); *see also* Compl. ¶ 33. Finally, under the Act, the new textual warnings and graphic-image labels (and the related requirements) were scheduled to take effect 15 months after issuance of the Rule. Act § 201(b) (note on amending 15 U.S.C. § 1333).

B. The Rule

1. Proposed Rule

On November 12, 2010, the FDA submitted for public comment a Proposed Rule unveiling therewith 36 graphic color images that could be displayed with the 9 new textual warnings created by Congress.[8] Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524; 69,534-69,535 (Nov. 12, 2010) (to be codified at 21 C.F.R. Part 1141); *see also* Compl. ¶¶ 36, 38; Defs.' Opp'n at 11. In addition, the Proposed Rule required cigarette packaging and advertising to include "a reference to a smoking cessation assistance resource" and set forth related requirements for what that

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manufacturer and the quantity of tobacco contained in the product. *See* Act § 101(b); *see also* Pls.' Mot. for PI at 2.

[8] The proposed images were not only in color, but some were also cartoon images, as opposed to staged photographs; and some were at least arguably enhanced, using either actors or technological augmentation to achieve the desired effect. *See* Compl. ¶ 38.

resource must provide. 75 Fed. Reg. 69,564 (proposing 21 C.F.R. § 1141.16(a)); *see also* Compl. ¶ 39. Finally, as part of its preliminary benefits analysis, the FDA estimated that "the U.S. smoking rate will decrease by ***0.212*** percentage points" as a result of the Proposed Rule,[9] 75 Fed. Reg. 69,543 (emphasis added), a statistic the FDA admits is "in general not statistically distinguishable from zero."[10] *Id.* at 69,546; *see also* Compl. ¶ 41.[11]

2. Final Rule

After a period of notice and comment in which the FDA reviewed more than 1,700 comments, it published a Final Rule on June 22, 2011. *See* 76 Fed. Reg. 36,628-36,629;

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[9] The FDA prefaced its calculation with the following statement: "Estimation of the effectiveness of the proposed rule (on reducing the future U.S. smoking rate) is subject to a large uncertainty that is not fully reflected in the benefits estimates appearing in the preceding sections, which only reflect different estimates of the value of a statistical life year." 75 Fed. Reg. 69,546. Yet despite whatever statistical uncertainty may have existed, the FDA nevertheless calculated and relied upon a 0.212 percentage-point change in the smoking rate as part of its justification for the Proposed Rule.

[10] Indeed, the FDA's estimated reduction in U.S. smoking rates decreased from .212% in the Proposed Rule to ***.088%*** in the Final Rule. *Compare* 75 Fed Reg. 69,543 *with* 76 Fed. Reg. 36,721. *See also* 76 Fed. Reg. 36,724 (further explaining the "FDA's estimate of a 0.088 percentage point reduction in the U.S. smoking rate"). Plaintiffs suggest that the decrease could be attributed to the FDA considering (for the first time) a confounding factor – the difference between Canadian and U.S. tax rates – in the Final Rule analysis. *See* Compl. ¶ 62.

[11] The Proposed Rule is replete with additional research and statistics on which the FDA relied to formulate its proposal. But a merits evaluation of that information – such as research regarding similar graphic warnings in Canada, *see* Compl. ¶¶ 40-46; Defs.' Opp'n at 18-20, 22-26, and an FDA-sponsored study assessing the effectiveness of its proposed graphic warnings, *see* Compl. ¶¶ 47-54; Defs.' Opp'n at 11, 27-30 – is not necessary here, where the threshold issue is whether injunctive relief is warranted based on plaintiffs' First Amendment claim – not whether defendants prevail on the merits.

Compl. ¶ 57. Of the 36 graphic images originally proposed, the FDA chose 9 for publication. *See* Compl. ¶¶ 57-58. The new graphic images, which will rotate according to an agency-approved plan, Act § 201(a) (amending 15 U.S.C. § 1333(c)(2)); Compl. ¶ 30, include color images of a man exhaling cigarette smoke through a tracheotomy hole in his throat; a plume of cigarette smoke enveloping an infant receiving a kiss from his or her mother; a pair of diseased lungs next to a pair of healthy lungs; a diseased mouth afflicted with what appears to be cancerous lesions; a man breathing into an oxygen mask; a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso; a woman weeping uncontrollably; and a man wearing a t-shirt that features a "no smoking" symbol and the words "I Quit." *See* Compl. ¶¶ 57, 59. An additional graphic image appears to be a stylized cartoon (as opposed to a staged photograph) of a premature baby in an incubator. *Id.* Plaintiffs allege, on information and belief, that many of these images are technologically manipulated,[12] enhanced, or animated, or that they depict actors to achieve the desired image. *See id.* ¶ 59; *see also* Tr. at 11:17-20. And indeed, the FDA cited these nine images' "salience" – defined at various points as a warning's ability to evoke emotion – as a primary selection criterion.[13] 76 Fed. Reg. at 36,639.

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[12] The FDA does not dispute that "some of the photographs were technologically modified to depict the negative health consequences of smoking," although it insists that "the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking." Defs.' Opp'n at 26 (quoting 76 Fed. Reg. at 36,696).

[13] The Rule reads, in pertinent part: "First, many of the proposed required warnings *elicited significant impacts on the salience measures (emotional and cognitive measures)*,

In addition to being paired with one of the nine new textual warnings introduced by Congress, each of the graphic images prominently displays "1-800-QUIT-NOW": a telephone number the FDA selected to fulfill its own regulatory obligation to offer smoking cessation assistance on each package. 76 Fed. Reg. 36,686-36,687, 36,754-36,755; *see also* Compl. ¶¶ 57, 60. Based on the 15-month implementation period set out by Congress, *see* Act § 201(a) (amending 15 U.S.C. § 1333), the new textual warnings and graphic images are scheduled to take effect for all cigarette packages manufactured on or after September 22, 2012, and for all cigarette packages introduced into commerce on or after October 22, 2012. *See* Act § 201(b) (note on amending 15 U.S.C. § 1333); *see also* Mot. for PI at 3. In response to the Final Rule, plaintiffs filed a Motion for Preliminary Injunction on August 19, 2011; defendants responded on September 9, 2011; and oral argument was held on September 21, 2011.

ANALYSIS

I. Standard of Review

The factors a court must consider in determining whether to grant injunctive relief

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which the research literature suggests are likely to be related to behavior change (Ref. 51). For example, the literature suggests that risk information is most readily communicated by messages that *arouse emotional reactions* (see Ref. 45), and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit (Ref. 44). The research literature also suggests that warnings that generate an *immediate emotional response* from viewers can result in viewers attaching a negative affect [sic] to smoking (i.e., feel bad about smoking), thus undermining the appeal and attractiveness of smoking (Ref. 45 and Ref. 40 at pp. 37-38)." 76 Fed. Reg. at 36,639 (emphasis added).

are, of course, familiar:[14] "(1) whether there is a substantial likelihood of success on the merits; (2) whether the movant will suffer irreparable harm if the injunction is not granted; (3) whether the injunction will substantially injure other interested parties; and (4) whether the public interest would be furthered by the injunction." *Ivax Pharms., Inc. v. FDA*, No. 04-1603, 2004 U.S. Dist. LEXIS 29223, at *1-2 (D.D.C. Sept. 17, 2004) (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998)).

Importantly, "[t]he party seeking a preliminary injunction need not prevail on each factor." *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 66 (D.D.C. 2010). Indeed, courts may apply the factors on a "sliding scale," *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009), and "[i]f the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Smoking Everywhere*, 680 F. Supp. 2d at 66 (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995)). A "very strong showing of irreparable harm," for example, absent "substantial harm to the non-movant" may warrant application of "a correspondingly lower standard . . . for likelihood of success." *Davis*, 571 F.3d at 1292. Similarly, "a greater likelihood of [the movant's] success will militate for a preliminary injunction unless particularly strong equities favor the [non-moving] parties." *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1035 (D.C. Cir. 2008).

As an initial matter, defendants challenge this Court's authority to award

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[14] The factors are the same under constitutional or APA review. *See* 5 U.S.C. § 705; Fed. R. Civ. P. 65; *see also Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010) ("Motions to stay agency action pursuant to these provisions are reviewed under the same standards used to evaluate requests for interim injunctive relief.").

injunctive relief in this case *at all*. *See, e.g.*, Defs.' Opp'n at 3, 35-37; Tr. at 38-41. Because plaintiffs ask the Court to postpone the effective date of the Rule for a period *after* final judgment – instead of requesting a stay of agency action *pending* final judgment – defendants contend that plaintiffs' request for preliminary injunctive relief is, by definition, inappropriate. *Id.* I disagree. *See, e.g.*, *Fed. Trade Comm'n v. Weyerhaeuser Co.*, 665 F.2d 1072, 1084 (D.C. Cir. 1981) (recognizing party's ability to challenge the validity of a law before its enforcement to avoid irreparable injury as deriving from "equity practice with a background of several hundred years").

Like plaintiffs, I reject the notion that this Court does not have the inherent equitable power to issue relief in this case. *See, e.g.*, Fed. R. Civ. P. 65; *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 834 (D.C. Cir. 1984) (a district court may "properly employ [] its inherent equitable powers . . . to prevent plaintiffs from suffering irreparable injury"); *see also* Reply at 22-23. Indeed, this Court's equitable powers extend even farther, "beyond the matters immediately underlying its equitable jurisdiction" to "decide whatever other issues and give whatever other relief may be necessary under the circumstances" and to "do complete rather than truncated justice." *Porter v. Warner Holdings Co.*, 328 U.S. 395, 398 (1946); *see also* Reply at 22. Thus, there is no genuine question about this Court's authority to issue injunctive relief in this case. That said, I turn to an analysis of plaintiffs' claims under the balancing test used to evaluate injunctive relief.

II. First Amendment Claim

At the outset, it is important to note that plaintiffs do not quarrel with the

substance of the nine new textual messages Congress created by statute. Tr. 16:11-12. Indeed, plaintiffs insist that they would not contest replacing the Surgeon General's warning, currently displayed on the side of cigarette packages, with any of Congress's nine new textual warnings. *Id.* at 9:24-25-10:1-3, 15:11-12. Plaintiffs do, however, oppose the placement of textual warnings which "confiscate" the front and back portions of cigarette packaging. *Id.* at 9:1-3. They further argue that the graphic images (and related placement requirements) promulgated in the FDA's Final Rule, *alone* and in combination with Congress's new textual warnings, violate the First Amendment. *Id.* at 10:20-23.

In particular, plaintiffs argue that the new Rule unconstitutionally compels speech, *see Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995), and that such speech does not fit within the "commercial speech" exception under which certain types of Government-mandated, informational disclosures are evaluated under a less restrictive standard, *see Zauderer v. Office of Disciplinary Counsel for Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985); *see also* Mot. for PI at 11-13. As a result, they argue, the Government's conduct must be analyzed under the strict scrutiny standard.[15] Mot. for PI at 11-13.

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[15] The parties fundamentally disagree on the applicable level of scrutiny. While plaintiffs advocate for application of strict scrutiny, they also argue that the Rule *fails* under any constitutional standard. *See* Mot. for PI at 11. And as defendants argue that the Rule is subject to no more than intermediate scrutiny, *see Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566 (1980), (but more likely a less restrictive review under *Zauderer*), they also insist that the Rule *withstands* any level of scrutiny. Defs.' Opp'n at 15.

Defendants, not surprisingly, disagree, contending that this case is so similar to a case filed and decided in the Western District of Kentucky that this Court's decision should be, in essence, dictated by the determinations made by the judge in that case. *See Commonwealth Brands, Inc. v. United States ("Commonwealth Brands")*, 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010) (considering, and rejecting, application of strict scrutiny to plaintiffs' First Amendment facial challenge to the graphic-warning statute); *see also* Defs.' Opp'n at 2 ("Plaintiffs' new suit reprises arguments already considered and rejected in *Commonwealth Brands*.").[16] I disagree.

Not only do I reject the Government's suggestion that this case is factually analogous to *Commonwealth Brands*,[17] but I would remind the Government that even decisions from other district courts in *our* Circuit have no binding effect on this Court. This case is, indeed, one of first impression in our Circuit – and one wholly separate, both factually and legally, from the *Commonwealth Brands* case. For that reason and for the

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[16] Although three of the current plaintiffs – R.J. Reynolds Tobacco, Lorillard, and Commonwealth Brands, were plaintiffs in *Commonwealth Brands* (in addition to other manufacturers and retailers not involved in this litigation), current plaintiffs Liggett Group and Santa Fe were not. Compl. ¶ 24 n.3.

[17] The facts of this case are readily distinguishable from those in *Commonwealth Brands*, which was briefed and decided *after* the Act was passed, but *before* the FDA's Rule was promulgated. Compl. ¶ 24, n.3. The *Commonwealth Brands* plaintiffs, as a result, made a facial challenge to the constitutionality of graphic warnings in general – but unlike plaintiffs in *this* case, they were incapable of challenging any of the nine graphic warnings the FDA ultimately selected. Moreover, because this case turns on facts that were not available to the *Commonwealth Brands* plaintiffs, it presents new questions of law and fact – and new applications of law to facts. That the Government does not argue for issue preclusion undermines its attempt to characterize these two cases as functionally equivalent. *See* Pls.' Reply at 4, n.6; *see also* Defs.' Opp'n at 14, n.7 (alluding to issue preclusion but discouraging the Court from deciding preclusive effect (if any) "[a]t this preliminary juncture").

others described below, the analysis and ruling in the *Commonwealth Brands* case is of little value here.

A. Plaintiffs Have a Substantial Likelihood of Success on the Merits.

1. Applicable Level of Scrutiny

Put simply, plaintiffs' likelihood of success on the merits turns on the level of constitutional scrutiny which governs the FDA's Rule mandating textual warnings and graphic images on cigarette packaging and advertisements.

A fundamental tenant of constitutional jurisprudence is that the First Amendment protects "both the right to speak freely and the right to refrain from speaking at all." *Wooley*, 430 U.S. at 714. A speaker typically "has the autonomy to choose the content of his own message." *Hurley*, 515 U.S. at 573. And, in fact, "[f]or corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion). Thus, where a statute "'mandates speech that a speaker would not otherwise make,' that statute 'necessarily alters the content of the speech.'" *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 651 (7th Cir. 2006) (quoting *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988)). As the Supreme Court itself has noted, this type of compelled speech is "presumptively unconstitutional." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 830 (1995).

In the arena of compelled commercial speech, however, narrow exceptions do allow the Government to require certain disclosures to protect consumers from "confusion or deception." *Zauderer*, 471 U.S. at 651 (quoting *In Re R.M.J.*, 455 U.S.

191, 201 (2002)). Indeed, courts apply a lesser standard of scrutiny to this narrow category of compelled speech, through which the Government may require disclosure only of "purely factual and uncontroversial information." *Zauderer*, 471 U.S. at 651. Even under this paradigm, however, compelled disclosures containing "purely factual and uncontroversial information" may still violate the First Amendment if they are "unjustified or unduly burdensome." *Id.*

Unfortunately for the Government, the evidence here overwhelmingly suggests that the Rule's graphic-image requirements are *not* the type of purely factual and uncontroversial disclosures that are reviewable under this less stringent standard. Indeed, the fact *alone* that some of the graphic images here appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of "purely factual." That the images were unquestionably designed to evoke emotion – or, at the very least, that their efficacy was measured by their "salience," which the FDA defines in large part as a viewer's emotional reaction, *see* Compl. ¶ 58 (citing 76 Fed. Reg. at 36,638-36,639) – further undercuts the Government's argument that the images are purely factual and not controversial, *see, e.g.*, Defs.' Opp'n at 22-29. Moreover, it is abundantly clear from viewing these images that the emotional response they were crafted to induce is calculated to provoke the viewer to quit, or never to start, smoking: an objective wholly apart from disseminating purely factual and uncontroversial information.[18] Thus, while the line between the constitutionally

[18] For example, and as plaintiffs suggested in their briefing and at the September 21 hearing, what does the image of a body on an autopsy table convey? *See* Mot. for PI at 3;

permissible dissemination of factual information and the impermissible expropriation of a company's advertising space for Government advocacy can be frustratingly blurry,[19] here – where these emotion-provoking images are coupled with text extolling consumers to call the phone number "1-800-QUIT" – the line seems quite clear.

Moreover, the disclosures in this case are unlike those that the Government endorsed in *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 114-16 (2d Cir. 2001), where the Second Circuit applied a rational basis test to a Vermont statute which compelled manufacturers to include informational text on certain products' labels to advise consumers about mercury content. Nor do they fit, more importantly, the *Zauderer* paradigm – to which the Government adamantly clings, *see* Defs.' Opp'n at 15-17 – under which the Supreme Court upheld a state requirement that attorney advertisements disclose "purely factual and uncontroversial information about the terms

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Defs.' Opp'n at 26; Pls.' Reply at 5-6; Tr. at 11:14-17, 12:1-10. A reasonable inference, based on the images and the text, would be that smoking leads to autopsies: a conclusion I do not believe the Government intends to promote, and one that the Government has not demonstrated to be accurate. Once again, the Government relies on emotion – that "smoking kills 443,000 Americans each year" and that the "autopsy image underscores this factual, noncontroversial information and is a good deal less 'disturbing' than photographs of the most common ravages of the diseases caused by [cigarettes]," Defs.' Opp'n at 26 – instead of offering a single shred of evidence to support the proposition that smoking causes autopsies. Ironically, the Government would likely fare better under constitutional scrutiny (at least with respect to the content of its warnings) by depicting the factual and accurate images it belittles in its brief.

[19] The Government repeatedly failed to answer this Court's question during oral argument about when the dissemination of purely factual, uncontroversial information crosses the line into advocacy, *see, e.g.*, Tr. at 50:9-11, 52:12, 53:8-9 (failing to answer the Court's question of why the Rule isn't "advocacy as opposed to simply a statement of fact that relates to the product so that people aren't in some way deceived").

under which [an attorney's] services w[ould] be available." 471 U.S. at 651. To the contrary, the disclosures mandated in this case are much more similar in form and function to those at issue in *Blagojevich*, 469 F.3d at 643, 652.[20] Although only persuasive, the Seventh Circuit's reasoning in *Blagojevich* is particularly instructive. There, a three-judge panel applied strict scrutiny to a state law which required video-game retailers to affix a four-square-inch sticker with the number "18" (representing age 18) on any game deemed "sexually explicit" under the statute. 469 F.3d at 643, 652. Just as the Seventh Circuit recognized that a compelled video-game label based on what the state deemed to be "sexually explicit" was "far more opinion-based than the question of whether a particular chemical is within any given product," *Blagojevich*, 469 F.3d at 652 (referencing *Sorrell*), so too are the graphic images promulgated as part of the FDA's rule a more subjective vision of the horrors of tobacco addiction. Indeed, neither the stickers in *Blagojevich* nor the graphic images here can be characterized as mere "disclaimers that deliver cold, hard facts." Tr. at 18:6. Thus, the Rule does not fit – neatly or otherwise – into the *Zauderer* exception for purely factual and uncontroversial information. As such, these images must withstand the strict-scrutiny analysis the Supreme Court imposes on Government regulations which compel commercial speech.

2. Analysis Under Strict Scrutiny

To withstand strict scrutiny, the Government carries the burden of demonstrating

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[20] While I by no means intend to suggest that a case about video-game regulations carries the serious healthcare implications present in a case regarding cigarette warning labels, the constitutional analysis is the same where, as here, the disclosure is neither purely factual nor uncontroversial.

that the FDA's Rule is narrowly tailored to achieve a compelling government interest. *See, e.g., A.N.S.W.E.R. Coal. v. Kempthorne*, 537 F. Supp. 2d 183, 195-96 (D.D.C. 2008) (citing *Boos v. Barry*, 485 U.S. 312, 322 (1988) and *Rosenberger v. Rector & Visitors of the Univ. of Va.*, 515 U.S. 819, 829 (1995)). Unfortunately, the Government fails to do so here.

First, an analysis of the Government's compelling interest – which is normally a *perfunctory* step in the strict-scrutiny analysis – has been seriously clouded by the Government's own explanation of its goals, which are, to say the least, unclear. To start, the Government professes that its primary purpose is "'to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements.'" Defs.' Opp'n at 23 (citing 76 Fed. Reg. at 36,697). This is particularly important, the Government argues, because "consumers with low levels of education" have trouble recalling text-only health information. Defs.' Opp'n at 16, 24; *see also* 75 Fed. Reg. at 69,531-69,532.

Yet the Government's stated purpose does not seem to comport with the thrust of its arguments, or with the evidence it offers to support the Rule. Indeed, the Government appears to have chosen this "informational" goal as its official purpose because it most closely mirrors the *Zauderer* exception and would thus be subject to a lesser standard of scrutiny. As best as I can discern, however, the Government's primary purpose is not, as it claims, merely to inform.[21] Instead, the Government – through its own data and, in

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[21] For example, the Government argues that "[t]the most relevant metric in evaluating the warnings is not their short-term impact on smoking rates, but the extent to

fact, its own words – evinces a purpose wholly separate from education. In particular, the Government spends much of its brief discussing the 18,000-consumer study that the FDA commissioned to help determine which of the 36 proposed graphic images it would ultimately select. *See* Defs.' Opp'n at 27-30. In so doing, the Government acknowledges that the study was *not* designed to assess whether the proposed graphic images would have a statistically significant impact on consumer awareness of smoking risks, but rather to "assess[] the *relative* impact of different warnings based on participants' exposure to one graphic warning on one occasion." *Id.* at 29 (emphasis in original). Thus, instead of focusing on its own alleged primary goal – providing information to consumers – the Government effectively admits that it looked only to *relative* impact, thus side-stepping the basic question of whether any singular graphic warning was effective on its own terms.[22] This fundamental failure, coupled with the Government's emphasis on the images' ability to provoke emotion, strongly suggests that the Government's *actual*

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which they more effectively convey information about health risks to consumers and potential customers." Defs.' Opp'n at 23. Yet it offers no evidence pointing to the FDA's attempt to *measure* improvement in this area, much less whether the warnings *actually* achieved the purported goal of increasing consumer awareness. Needless to say, generalized scientific literature and the "experiences of countries such as Canada, Australia, and the United Kingdom" (none of which afford First Amendment protections like those found in our Constitution), *id.* at 24, say nothing about the nine graphic images at issue in this case.

[22] To be sure, the Government's reliance on Canadian studies or scientific studies of graphic warnings *in general* does not speak to the effectiveness (however that is measured), and certainly not to the constitutionality, of the 36 proposed graphic images or the 9 images ultimately selected. *See, e.g.*, Defs.' Opp'n at 27-30.

purpose is not to inform, but rather to advocate a change in consumer behavior.[23] Fortunately, however, identifying the Government's precise interest – and evaluating whether it is "compelling"[24] – is not, in fact, essential at this preliminary stage of the litigation, because under any scenario the Rule hardly appears to be narrowly tailored to achieve the Government's purpose. How so?

First, the sheer size and display requirements for the graphic images are anything but narrowly tailored. Although it is true that Congress mandated the new images to occupy the top 50% of the front and back panels of all cigarette packages and the top 20% of printed advertising, Act § 201(a) (amending 15 U.S.C. § 1333(a)(2),(b)(2)), and charged the FDA with implementing a final rule consistent with its mandate, *see id.* (amending 15 U.S.C. § 1333(d)), doing so does not enable this requirement to somehow automatically pass constitutional muster.[25] Appropriating the top 50% of the front *and*

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[23] As plaintiffs point out, the Government's intent is "irreconcilable with its own admissions on the record that it chose warnings that scored high on the FDA Study for 'salience,' defined as an image's tendency to make viewers 'depressed, discouraged, and afraid,' 'arouse fear,' 'provoke[] a highly emotional response,' trigger 'greater negative emotional reactions,' or 'confer negative feelings about smoking.'" Pls.' Reply at 7 (quoting 76 Fed. Reg. at 36,638-36,639).

[24] Suffice it to say that a Government interest in disseminating information to consumers is more easily deemed "compelling" than is an interest in changing consumer behavior.

[25] For this reason, the Government's argument that the "FDA had no authority to second-guess [Congress's] legislative determination," Defs.' Opp'n at 32, does not advance its case. The FDA may not promulgate Rules that violate the Constitution, even as it attempts to comply with legislative requirements. Moreover, it is disingenuous for the Government to argue that the FDA had *no* discretion in formulating this rule; Congress specifically vested the Secretary with sufficient discretion to allow narrower tailoring in the Final Rule. *See, e.g.*, Act § 201 (amending 15 U.S.C. § 1333(d)).

back of all cigarette packages manufactured and distributed in the United States is hardly a directive narrowly designed to achieve the Government's purpose (whatever it might be). To the contrary, the dimensions *alone* strongly suggest that the Rule was designed to achieve the very objective articulated by the Secretary of Health and Human Services: to "rebrand[] our cigarette packs," treating (as the FDA Commissioner announced last year) "every single pack of cigarettes in our country" as a "mini-billboard."[26] Mot. for PI at 6 (citing a June 2001 press briefing with Sec. Sebelius, and an FDA Tobacco Strategy Announcement). A "mini-billboard," indeed, for its obvious anti-smoking agenda! Suffice it to say that if the Seventh Circuit determined in *Blagojevich* that a four-square-inch sticker "*literally* fail[ed] to be narrowly tailored" because it "cover[ed] a substantial portion of the box," 469 F.3d at 652, plaintiffs are highly likely to prevail on the same argument here.[27]

Similarly, it is easy to conclude that the content of the graphic images chosen are not likely to survive a "narrowly tailored" analysis. Defendants, for their part, argue that plaintiffs object to *any* type of graphic images whatsoever. *See, e.g.*, Defs.' Opp'n at 22. But that is not actually so. And although plaintiffs may, in fact, object to any graphic image of the size or placement mandated by the Final Rule, they do, at least, concede two

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[26] One can only wonder what the Congress and the FDA might conjure for fast food packages and alcohol containers if, like the Canadian government, they were not compelled to comply with the intricacies of our First Amendment jurisprudence.

[27] As *Blagojevich* nicely summarized, "[c]ertainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's unjustified requirement of the four square-inch '18' sticker." 469 F.3d at 652.

reasonable means of disseminating accurate information in a more narrowly tailored way. First, they could publish a graph demonstrating the difficulty of quitting smoking by showing the correlation between the number of people who try to quit and the percentage who actually do. *See* Tr. at 20:5-8. Or, for example, plaintiffs could publish a "graphic that depicts the types of harms that befall children if they are exposed to secondhand smoke or the types of birth defects that arise, and their likelihood, if mothers smoke during the course of pregnancy." *Id.* at 20:18-21. Though other alternatives surely exist, a prolonged examination of those arguments is not necessary at this point, where it is quite clear that the Rule's graphic-image requirements in no way suggest the slightest attempt to narrowly tailor the display or presentation of the graphic images Congress mandated.[28]

In short, the Government has neither carried its burden of demonstrating a compelling interest, nor demonstrated how the Rule is narrowly tailored to achieve a constitutionally permissible form of compelled commercial speech. As a result, plaintiffs are likely to succeed on the merits and this factor weighs heavily in favor of awarding injunctive relief.

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[28] To be sure, the ineffectiveness, size, placement, and content of the warnings are, individually, evidence that the graphic warnings are not narrowly tailored. Combined, these factors significantly increase the likelihood that the graphic warnings cross the line from information to advocacy. That each warning brandishes the "1-800-QUIT-NOW" smoking-cessation hotline only enhances plaintiffs' argument that the FDA has "conscript[ed] [tobacco manufacturers] into an anti-smoking brigade." Tr. at 33:19-20.

And while the Congress and the FDA might be genuinely challenged to craft tailored images that pass constitutional muster, that does not excuse them from striving to do so in the first instance. Indeed, our First Amendment jurisprudence in this area of compelled commercial speech should have *compelled* them to at least try!

B. Plaintiffs Offer Sufficient Evidence of Irreparable Harm Absent Injunctive Relief.

It is undisputed that our Circuit "has set a high standard for irreparable injury." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). In addition to demonstrating an injury that is "both certain and great," the moving party "must show that the injury complained of is of such imminence that there is a 'clear and present'" need for equitable relief to prevent irreparable harm." *Id.* (quoting *Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)). Indeed, a plaintiff must show that it will suffer harm that is "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981).

Plaintiffs here offer two main arguments to support their claim of irreparable harm. First, they point to the monetary harm they will incur during the 15-month preparation period necessary to comply with the Rule. *See* Mot. for PI at 14-16. In particular, plaintiffs offer sworn declarations attesting to the tens of millions of dollars they will be forced to spend redesigning existing cigarette packaging,[29] purchasing and engraving blank printing cylinders, and embossing new packaging (among other costs). *Id.* Specifically, and as defendants point out, plaintiffs submit declarations that estimate the aggregate monetary harm somewhere around $20 million. Defs.' Opp'n at 42. In addition, plaintiffs offer sworn declarations attesting to the thousands of employee hours

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[29] Plaintiff R.J. Reynolds avers that it alone must modify 480 distinct package designs. *See* Mot. for PI at 14 (citing O'Brien Decl. ¶ 5).

the companies will be forced to expend in preparation for full compliance with the Rule.[30] Mot. for PI at 16.

Unfortunately for plaintiffs, however, the standard for irreparable economic harm in our Circuit is so demanding that the proof of even tens of millions of dollars in economic detriment does not necessarily suffice. Indeed, "[r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the *very existence of the movant's business*." *Wisc. Gas. Co.*, 758 F.2d at 674 (emphasis added). And as defendants note, plaintiffs' aggregate, estimated cost of compliance represents approximately "twelve one-hundredths of one percent of plaintiffs' combined annual sales as reported for 2010." Defs.' Opp'n at 42. Accordingly, plaintiffs do not demonstrate irreparable injury based on economic harm *alone*.

Plaintiffs do, however, offer a second – and more persuasive – argument to demonstrate irreparable harm: their inability to recover costs from the FDA. Indeed, if this Court denies preliminary injunctive relief and another court overturns that decision, or even if this Court denies preliminary injunctive relief but later grants relief for plaintiffs on the merits, plaintiffs would be an injured party without legal recourse. *See* Mot. for PI at 16.

As such, plaintiffs' argument here fits well within the definition of irreparable harm that I previously recognized and described in *Smoking Everywhere*, 680 F. Supp. 2d at 77 n.19. There, I determined that the FDA's APA violation resulted in irreparable

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[30] For example, plaintiff R.J. Reynolds alone anticipates expending over 4,000 hours of employee time to ensure compliance with the Rule. Mot. for PI at 16.

economic injury – even absent a threat to plaintiffs' viability – "because plaintiffs c[ould] not recover money damages against [the] FDA." *Id; see also Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) ("While the injury to plaintiffs is admittedly economic, there is no adequate compensatory or other corrective relief that can be provided at a later date, tipping the balance in favor of injunctive relief.") (internal citation and quotations omitted). Plaintiffs' harm is no different here.[31] Absent injunctive relief (and especially in light of plaintiffs' likelihood of success on the merits), plaintiffs have thus demonstrated that they will suffer irreparable harm.

In addition, plaintiffs appropriately argued at the September 21, 2011 hearing that the harm flowing from a First Amendment violation is *per se* irreparable. *See, e.g.*, *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.") (citing *N.Y. Times Co. v. United States*, 403 U.S. 713 (1971)); *see also* Tr. at 24:6-7. Where, as here, plaintiffs are likely to prevail on the merits of their constitutional claim, and where their "First Amendment interests are either threatened or in fact being impaired at the time relief is sought," *Chaplaincy of Full Gospel Churches*, 454 F.3d at 301 (citing *Nat'l Treas. Emps. Union v. United States*, 927 F.2d 1253, 154-55 (D.C. Cir. 1991) and quoting *Wagner v. Taylor*, 836 F.2d 556, 577 n.76 (D.C. Cir. 1987) and *Elrod*,

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[31] Indeed, *Wisconsin Gas* implicitly endorses this concept in its discussion of how corrective relief and recoverable loss militate against injunctive relief. *See* 758 F.2d at 674.

427 U.S. at 373), there is more than a sufficient showing of irreparable harm.[32] To that end – and contrary to defendants' protestations otherwise, *see* Defs.' Opp'n at 39-40 – the harm plaintiffs suffer is, in fact, "serious in terms of its effect," *Coal. For Common Sense in Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008), precisely because their First Amendment rights have been abridged. Such harm is *not*, as defendants conveniently claim, merely "the ordinary costs of complying with regulations." Defs.' Opp'n at 39. It is the residual effect of unconstitutionally compelled commercial speech designed to advocate, at a company's expense, a competing policy agenda. Thus, plaintiffs have demonstrated that they will suffer irreparable harm in the absence of preliminary relief, and this factor also weighs in favor of granting an injunction.

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[32] The Government argues that even an alleged First Amendment violation is not *per se* irreparable harm where, as here, the FDA's Rule is operative, but where plaintiffs have not yet printed the new warnings (and thus have not yet realized the costs associated with them). Specifically, the Government argues that "this isn't the case in which any speech either is happening or not happening within the coming year," Tr. at 43:4-6, and thus plaintiffs' speech has not been compelled – at least not yet.

The Government's argument, however, once again misses the mark. Under its reasoning, plaintiffs would suffer no harm – even facing implementation of a Rule that violates the First Amendment – until the point of implementation at which new printing plates were designed and forged, or perhaps until every cigarette package in the country were imprinted with the new graphic warnings and all related costs were incurred. At that point, however, plaintiffs would have suffered harm with no possibility of economic recourse (a principle which I have already discussed), and the Rule would, in essence, escape the constitutional scrutiny and preliminary review that could afford *any* type of meaningful relief. A system of justice premised on this type of reasoning defies common sense and is fundamentally unfair! Put simply, defendants cannot separate the Rule's effective date from the point at which plaintiffs begin suffering harm (whether constitutional or economic). Faced with a Rule which compels speech and threatens their First Amendment rights, plaintiffs are not required to sit idly and wait for irreparable and irretrievable harm to occur before they may seek relief.

C. Injunctive Relief Will Not Substantially Injure Other Interested Parties, Including the Public or the Government.

Although the two most critical factors weigh in favor of granting injunctive relief, other parties' interests – and the prejudices other parties might suffer – must also be evaluated and weighed against the factors supporting an injunction.

Defendants argue that the delay resulting from a grant of injunctive relief harms the public because "*[e]ach day*, nearly 4,000 Americans under the age of 18 experiment with cigarettes for the first time, and approximately 1,000 children become new daily smokers." Defs.' Opp'n at 43 (emphasis in original). Consistent with its briefing and oral argument, the Government unfortunately – and once again – trumpets its appeal to emotion instead of focusing on the discrete legal issue before the Court: whether the public will be prejudiced by a temporary delay in the Rule's implementation.[33] Notwithstanding its obvious desire to limit, if not eradicate, the use of tobacco, the Government utterly fails to address the real issue at hand, and in the process gives short shrift to Congress's own instruction for a 15-month implementation period. *See* 76 Fed. Reg. 36,703.

Put simply: based on the existing record, Congress demonstrated no real urgency when it passed the graphic-warning statute and vested the FDA with authority to promulgate the graphic-warning rule. To the contrary, Congress provided a measured,

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[33] Of course, the temporary delay caused by a preliminary injunction could ultimately turn into a permanent delay if this Court determines, on the merits, that the Rule is unconstitutional or violates the APA. If that were the case, however, defendants could hardly argue that the public suffered prejudice from injunctive relief since *that very relief* would preserve the public's First Amendment rights.

multi-stage timeline in which the FDA had *up to two years* to issue a Final Rule, and a *15-month* implementation period before the Final Rule and its related requirements took effect. Pls.' Mot. for PI at 19. The Government, for its part, has pointed to *no* evidence supporting its bare assertion that "the fact that Congress gave 15 months doesn't mean that every month of that is required." Tr. at 40:22-24.[34] Thus, I can afford little weight to defendants' argument that a delay specifically contemplated and mandated by Congress could prejudice the public, or even the Government itself.

Finally, and most importantly, the constitutional protections an injunction would afford plaintiffs far outweigh any incidental prejudice the public (or indeed, the Government) could hypothetically suffer as a result of preliminary injunctive relief. After all, "the public clearly has an interest in free speech," and therefore "the public interest . . . will be served by ensuring that plaintiffs' 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) (Green, J.). Indeed, as plaintiffs noted during oral argument and again in their supplemental pleading, Congress did not specifically contemplate the First Amendment implications when formulating its statute, much less whether the statute or the FDA's subsequent Rule might violate it. *See, e.g.*, Tr. at 72:1-23; *see also* Pls.' Supp. Memo. In Supp. of Pls.' Mot. for Prelim. Inj., Sept. 30, 2011, at 1-2 [Dkt. #32] ("We have been unable to identify any indication in the legislative history that Congress considered the

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[34] Moreover, that the FDA used the full two-year period to promulgate the Final Rule undercuts any argument that implementation is urgent. *See* Mot. for PI at 19.

First Amendment implications of these changes or of the warnings requirement generally.").[35] And when one considers the logical extension of the Government's defense of its compelled graphic images to possible graphic labels that the Congress and the FDA might wish to someday impose on various food packages (*i.e.*, fast food and snack food items) and alcoholic beverage containers (from beer cans to champagne bottles), it becomes clearer still that the public's interest in preserving its constitutional protections – and, indeed, the Government's concomitant interest in not violating the constitutional rights of its citizens – are best served by granting injunctive relief at this preliminary stage. Thus, like the two before them, the final two factors weigh heavily in favor of an injunction.

CONCLUSION

This case poses a constitutional challenge to a bold new tack by the Congress, and the FDA, in their obvious and continuing efforts to minimize, if not eradicate, tobacco use in the United States. Notwithstanding the potential legal and financial ramifications of this challenge, the Government, for reasons known only to itself, is unwilling to voluntarily stay the effective date of this Rule until the Judicial Branch can appropriately review the constitutionality of the Government's novel – and costly – approach to regulating tobacco packaging and advertising. Thus, this Court must – and will – act to

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[35] Plaintiffs make several other persuasive arguments dispelling the notion that injunctive relief would harm the public, but those arguments do not merit full discussion here. *See id.* at 19-21 (arguing that the Surgeon General's warnings sufficiently inform consumers about the health risks of tobacco and that the Government offers no empirical evidence that the new graphic warnings "reduce consumption or change smoking behavior").

preserve the status quo until it can evaluate, on the merits (and without incurring irreparable harm to those companies genuinely affected), the constitutionality of the commercial speech that these graphic images compel. Therefore, for all the foregoing reasons, this Court concludes that the plaintiffs have demonstrated: (1) a substantial likelihood of success on the merits; (2) that they will suffer irreparable harm absent injunctive relief; (3) that neither the Government, nor the public, will suffer any comparable injury as a result of the relief sought; and (4) that the public's interest in the protection of its First Amendment rights against unconstitutionally compelled speech will be, in fact, furthered. Accordingly, the plaintiffs' Motion for Preliminary Injunction [Dkt. #11] is GRANTED. An order consistent with this decision is attached herewith.

RICHARD J. LEON
United States District Judge