IN THE 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.

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.

Civil Action No. 11-01482 (RCL)

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
[ORAL ARGUMENT REQUESTED]

On June 22, 2011, the Food and Drug Administration ("FDA") published a Final Rule implementing Section 201 of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (the "Act"). *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("the Rule"). The Rule requires that Plaintiffs radically change all of their cigarette packaging and advertising, so as to prominently display nine new textual warnings along with disturbing and emotionally-charged graphic images. These graphics, which include images of a body on an autopsy table and of diseased body parts, are designed to shock, disgust, and frighten adult consumers of cigarettes. The new warnings also include a telephone hotline reference that directly admonishes smokers to

"QUIT-NOW" and must occupy the top 50% of the front and back panels of each and every package and the top 20% of all printed advertising.

The new warnings regime imposed by the Rule crosses the line into anti-smoking advocacy. The purpose and effect of the warnings is to drown out Plaintiffs' own constitutionally protected speech about their lawful products and replace it with the Government's emotionally-charged anti-smoking message. FDA's reasoning in support of the selected warnings, moreover, is illogical, not supported by the record, and contradictory, and ignores less intrusive but equally effective alternatives. Finally, FDA failed to provide sufficient notice to allow meaningful comment on the Rule. Accordingly, Plaintiffs in the above-captioned case have challenged the Rule as a violation of their rights under the First Amendment and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553(b)(3), 705, 706(2)(A).

The Act also imposes a related set of labeling requirements. These requirements (hereafter the "Related Requirements") require that cigarette packaging display:

1. "the name and place of business of the tobacco product manufacturer, packer, or distributor," *see* Act § 101(b) (inserting Food, Drug, and Cosmetic Act ("FDCA") § 903(a)(2)(A)), 21 U.S.C. § 387c(a)(2)(A);

2. "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(B)), 21 U.S.C. § 387c(a)(2)(B);

3. "an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(C)), 21 U.S.C. § 387c(a)(2)(C); and

4. where applicable, "the statement 'Sale only allowed in the United States,'" *see* Act § 301, FDCA § 920(a), 21 U.S.C. § 387t(a).

The Act likewise mandates changes to the substantive content of the text of the warnings. *See* Act § 201, 123 Stat. at 1842-43 (listing nine new textual warnings).

The Act provides for a 15-month implementation period following the issuance of the Rule. Consequently, the new textual and graphic warnings and Related Requirements will currently become effective for all cigarette packages manufactured on or after September 22, 2012, and introduced into commerce on or after October 22, 2012. *See* Act § 201(b), 15 U.S.C § 1333, note (setting effective date of new textual and graphic warnings required by sections 4(a) and 4(d) of the Federal Cigarette Labeling and Advertising Act ("FCLAA")); Act § 103(q)(5), 21 U.S.C. § 387c, note (setting same effective date for the Related Requirements of FDCA § 902(a)(2)(A)-(C)); Act § 301, 21 U.S.C. § 387t (setting same effective date for the Related Requirement of FDCA § 920(a)).

Congress's use of a single implementation date for the new textual and graphic warnings and the Related Requirements demonstrates an intent that manufacturers not be subjected to multiple, costly packaging overhauls. The length of this implementation period, moreover, reflects Congress's recognition that it will take Plaintiffs a substantial amount of time to overhaul completely all of their cigarette packaging. Congress's assessment was accurate: it will take more than a year of vigorous efforts to implement the Rule, at a cost of tens of millions of dollars. *See* Declaration of J. Brice O'Brien; Declaration of Stephen Klepper; Declaration of Victor D. Lindsley, III; Declaration of William Melton; Declaration of Gregory A. Sulin; Declaration of David D. Depalma.

If the new warnings required by the Rule were to be struck down or modified in any material respect, however, Plaintiffs' costly and time-consuming implementation process would have to begin anew and the costs already incurred to comply with the current Rule would constitute irreparable injury. Accordingly, Plaintiffs respectfully move this Court pursuant to 5 U.S.C. § 705, Rule 65 of the Federal Rules of Civil Procedure, and this Court's Local Rule 7, for

entry of a preliminary injunction postponing the effective date of the new textual and graphic warnings and Related Requirements in order to preserve the status quo pending judicial review of the Rule. In support of this Motion, Plaintiffs are filing a Memorandum of Points and Authorities, along with six Declarations and a Proposed Order. Plaintiffs request oral argument on this Motion.

As explained more fully in the supporting Memorandum filed herewith, Plaintiffs satisfy the standard for preliminary relief under 5 U.S.C. § 705 and Rule 65.

1. Plaintiffs' challenge to the Rule has a high probability of success on the merits. The Rule infringes Plaintiffs' right to engage in free speech, including commercial speech with lawful adult customers, under the First Amendment. The Rule is also arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A), in that FDA justified the warnings it selected on grounds that were illogical, not supported by the record, and contradictory, and ignored less intrusive but equally effective alternatives. Moreover, the Rule was promulgated without sufficient notice and opportunity for comment, in violation of 5 U.S.C. § 553(b)(3). The merits of Plaintiffs' First Amendment and APA claims are set forth in detail in their Motion for Summary Judgment and Permanent Injunction, filed herewith.

2. Absent preliminary relief, Plaintiffs will suffer immediate and irreparable harm. Plaintiffs must immediately begin, and indeed have already begun, the process of implementing the changes needed to comply with the current Rule by the effective date. Those substantial expenditures will have been wasted if this Court should hold the Rule to be invalid in whole or in part. Plaintiffs can be protected from such irreparable injury only by the issuance of injunctive relief postponing the effective date of the new warnings regime and the Related Requirements until 15 months after the validity of the Rule has been determined by this Court. Congress

intended that Plaintiffs have 15 months to produce new labels after they knew what the Rule would require, and that is all Plaintiffs are seeking.

3. The equities clearly favor the grant of injunctive relief in this case. Postponing the effective date of the new warnings and Related Requirements to preserve the status quo until after this Court has ruled on the merits of Plaintiffs' claims would harm neither Defendants nor the public. FDA itself has conceded that its estimates of the Rule's impact on smoking rates are "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. Moreover, FDA has demonstrated no urgency in promulgating the Rule, and the Act itself provided for a relatively lengthy rulemaking and implementation period. Moreover, prior to implementation of any new warnings, all cigarette packaging and advertising will continue to bear the current health warnings which, combined with the vast array of other information available, have produced effectively universal awareness of the health risks of smoking. A short additional postponement of the effective date allowing Plaintiffs to continue using their current packaging and advertising until 15 months following a decision by this Court would thus have no material adverse impact from a public health perspective.

4. The relief Plaintiffs seek is in the public interest as it would further both core First Amendment principles and the due process principle of permitting parties to obtain judicial review of unlawful regulations before being injured by them.

Plaintiffs therefore respectfully request that the Court grant this Motion and enter an order (a proposed order is attached), pursuant to 5 U.S.C. § 705 and Rule 65 of the Federal Rules of Civil Procedure, containing the following injunction:

1. That Defendants are enjoined from enforcing against Plaintiffs in this case, until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims,

the effective date of the new textual and graphic warnings implemented by the regulation published at 76 Fed. Reg. 36,628 (June 22, 2011) and required by Section 201(a) of the Tobacco Control Act;

2. That Defendants are enjoined from enforcing against Plaintiffs in this case, until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims, the effective date of the following statutory provisions, which impose the stated labeling requirements:

   (a) "the name and place of business of the tobacco product manufacturer, packer, or distributor," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(A)), 21 U.S.C. § 387c(a)(2)(A);

   (b) "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(B)), 21 U.S.C. § 387c(a)(2)(B);

   (c) "an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(C)), 21 U.S.C. § 387c(a)(2)(C); and

   (d) where applicable, "the statement 'Sale only allowed in the United States,'" *see* Act § 301, FDCA § 920(a), 21 U.S.C. § 387t(a); and

3. That Plaintiffs in this case are permitted to continue using their current cigarette packaging and advertising until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims.

Plaintiffs have conferred with defendants on this motion. *See* LCvR 7(m). Defendants do not agree to the relief sought herein. The parties have also conferred regarding the appropriate briefing schedule. Under the Local Rules, Defendants have 7 days to oppose Plaintiffs' motion for a preliminary injunction. LCvR 65.1(c). Plaintiffs offered to extend the deadline for Defendants' opposition from 7 days to 21 days, with Plaintiffs reply brief due 14 days thereafter. Defendants stated that such schedule would be insufficient. However, as

Plaintiffs explained to Defendants, and as the accompanying memorandum (pp. 21-24) makes clear, in order to avoid having to expend significant amounts of money necessary for them to comply with the current effective date, Plaintiffs would need this Court to resolve the preliminary injunction motion by the end of October 2011. Therefore, a reasonably expeditious briefing schedule is necessary. To avoid unnecessary motion practice concerning the schedule, Plaintiffs respectfully request that the Court hold a short conference at its earliest convenience to set a briefing schedule on this motion.

Respectfully Submitted,

Dated: August 19, 2011

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R.J. REYNOLDS TOBACCO COMPANY, LORILLARD TOBACCO COMPANY, COMMONWEALTH BRANDS, INC., LIGGETT GROUP LLC, and SANTA FE NATURAL TOBACCO COMPANY, INC., Plaintiffs, v. 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.	Civil Action No. 11-01482 (RCL)

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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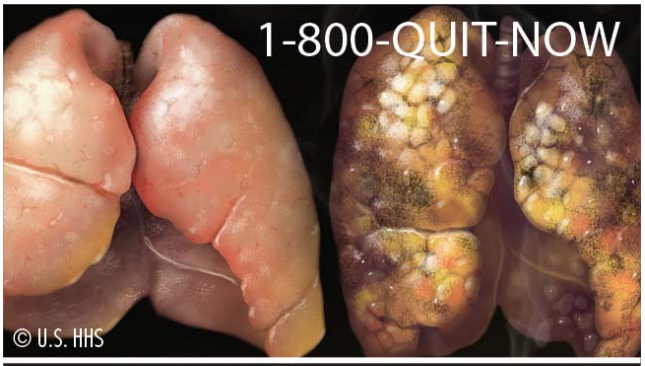
BACKGROUND

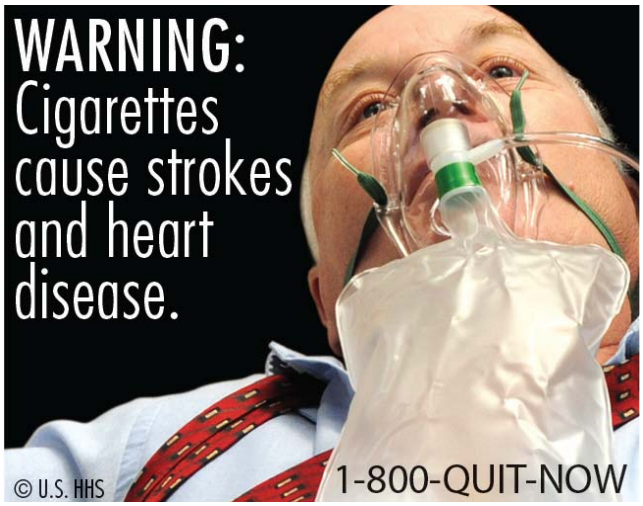
For more than 45 years, cigarettes sold in the United States have been accompanied by various Surgeon General's Warnings, and Plaintiffs have never challenged any of them. On June 22, 2011, the Food and Drug Administration ("FDA") published a Final Rule requiring that manufacturers of cigarette products, including Plaintiffs, radically change all of their cigarette packaging and advertising, so as to prominently display nine new textual warnings along with disturbing and emotionally-charged graphic images. These graphics, which include images of a body on an autopsy table and of diseased body parts, are designed to shock, disgust, and frighten adult consumers of cigarettes. The new graphic warnings also include a telephone hotline reference that directly admonishes smokers to "QUIT-NOW" and must occupy the top 50% of the front and back panels of each and every package and the top 20% of all printed advertising. *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("the Rule").[1]

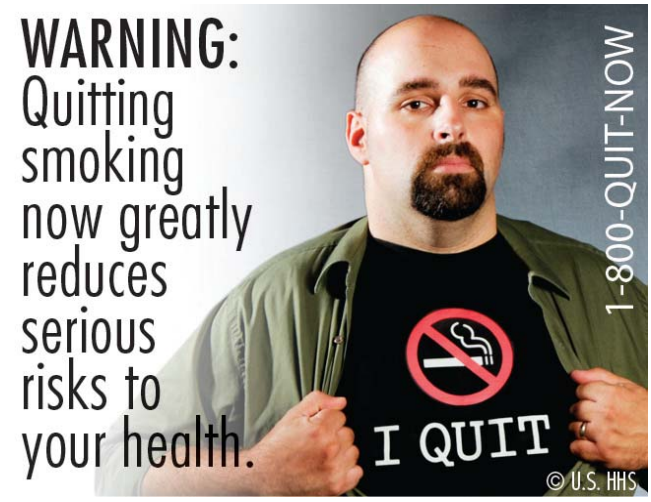
[1] The new warnings must be placed on any "Package," which the Rule defines to include "a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers." 76 Fed. Reg. at 36, 753. Thus, for a manufacturer like R.J. Reynolds, the Rule requires changes to no fewer than 480 distinct package designs. *See* Declaration of J. Brice O'Brien ¶ 5.



WARNING: Cigarettes cause fatal lung disease.

WARNING:
Cigarettes cause cancer.





The Act also contains a related set of labeling requirements (hereafter the "Related Requirements"), which require that cigarette packaging display:

1. "the name and place of business of the tobacco product manufacturer, packer, or distributor," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(A)), 21 U.S.C. § 387c(a)(2)(A);

2. "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(B)), 21 U.S.C. § 387c(a)(2)(B);

3. "an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(C)), 21 U.S.C. § 387c(a)(2)(C); and

4. where applicable, "the statement 'Sale only allowed in the United States,'" *see* Act § 301, FDCA § 920(a), 21 U.S.C. § 387t(a).

Likewise, the Act mandates changes to the substantive content of the text of the warnings. *See* Act § 201, 123 Stat. at 1842-43 (listing nine new textual warnings).

The Act provides for a 15-month implementation period. *See* Act § 201(b), 15 U.S.C § 1333, note (setting effective date of new textual and graphic warnings required by FCLAA §§ 4(a), (d)); Act § 103(q)(5), 21 U.S.C. § 387c, note (setting same effective date for the Related Requirements of FDCA § 902(a)(2)(A)-(C)); Act § 301, 21 U.S.C. § 387t (setting same effective date for the Related Requirement of FDCA § 920(a)). And FDA has agreed that this 15-month implementation period is necessary. *See* 76 Fed. Reg. at 36,703. Consequently, the new warnings and Related Requirements will currently become effective for all cigarette packages manufactured on or after September 22, 2012, and introduced into commerce on or after October 22, 2012.

The new "warnings" imposed by the Rule are unprecedented. They do not convey purely factual and uncontroversial information to assist consumers in making informed decisions. Instead, the "warnings" are unbridled advocacy, plainly intended to drown out Plaintiffs' speech about their products with the Government's message: "Don't Buy This Product." Indeed, even FDA concedes that the Rule will ensure that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's anti-smoking message.[2] Or, as HHS Secretary Sebelius phrased it, the warnings effectively "rebrand[] our cigarette packs."[3] This is

[2] FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010), appearing at htttp://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm.

[3] Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011) ("Press Briefing"), http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser.

precisely the type of compelled speech that the First Amendment prohibits. *See, e.g., Wooley v. Maynard*, 430 U.S. 705, 715 (1977) (holding that the State may not use another person's "personal property as a 'mobile billboard' for the State's ideological message"). Moreover, FDA justified the warnings it selected on grounds that were illogical, not supported by the record, and contradictory, and ignored less intrusive but equally effective alternatives. Finally, FDA failed to provide sufficient notice to allow meaningful comment on the Rule. Plaintiffs have therefore challenged the Rule as violative of their rights under the First Amendment and as arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 705, § 706(2)(A).

It will take Plaintiffs more than a year of vigorous efforts, at a cost of tens of millions of dollars, to redesign, order, install and test equipment capable of printing the new warnings in the colors and styles required by the Rule. *See* Declaration of J. Brice O'Brien ¶ 8; Declaration of Stephen Klepper ¶ 20; Declaration of William Melton ¶¶ 9-12; Declaration of Gregory A. Sulin ¶ 7; Declaration of David D. Depalma ¶ 12. All of this money will be irretrievably lost if, as Plaintiffs believe, the Rule is invalid. Plaintiffs therefore seek preliminary injunctive relief to preserve the status quo pending the Court's review of the challenged Rule, so as to enable the judicial process to move forward without causing irreparable injury to Plaintiffs. Specifically, Plaintiffs request that the Court postpone the effective date of the new warnings and Related Requirements until fifteen months after the Court has ruled on Plaintiffs' challenge, to ensure that Plaintiffs' redesign and implementation of new packaging and advertising requirements reflect the requirements of the Rule as reviewed and upheld or modified by the Court.

A short additional postponement of the effective date would have no material adverse impact from a public health perspective. FDA has demonstrated no urgency, promulgating the Rule as late as was permissible under the Act's relatively lengthy rulemaking and

implementation period. And FDA's own estimate of the impact of the Rule on smoking prevalence is "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. Moreover, during the period of review by this Court, all cigarette packaging and advertising will continue to bear the current health warnings which, combined with the vast array of other information available, have produced effectively universal awareness of the health risks of smoking.

Accordingly, Plaintiffs seek preliminary injunctive relief under the APA and Federal Rule 65 to preclude enforcement of the new warnings and Related Requirements and allow Plaintiffs to continue using their current packaging and advertising until 15 months following a decision by this Court.

ARGUMENT

It has long been recognized that, where a party challenges the validity of a law before its enforcement, courts have the power to issue a preliminary injunction suspending enforcement of the law, so that a plaintiff with a colorable claim can avoid irreparable injury pending judicial review. *Fed. Trade Comm'n v. Weyerhaeuser Co.*, 665 F.2d 1072, 1084 (D.C. Cir. 1981) (noting that the power to issue preliminary injunctive relief preserving the status quo derives from "'equity practice with a background of several hundred years of history'" (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944))). Moreover, the Administrative Procedure Act ("APA") affirms that, in light of the complexity of modern regulatory requirements, this traditional power is available to toll the commencement of regulations that are not yet effective pending judicial review. Specifically, § 705 of the APA provides that:

> On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court . . . may 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.

5 U.S.C. § 705.

As this Court has explained:

> The factors that the Court must consider in determining whether to grant relief under 5 U.S.C. § 705 are the same as those considered in whether to grant injunctive relief under Fed. R. Civ. P. 65. These factors are: (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 29233, at *1-2 (D.D.C. Sept. 17, 2004) (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998)); *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.").

Courts typically apply the foregoing factors on a "sliding scale." *Davis v. Pension Benefit. Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009). That is, "if the movant makes a very strong showing of irreparable harm and there is no substantial harm to the non-movant, then a correspondingly lower standard can be applied for likelihood of success." *Id.* at 1292. Likewise, "a greater likelihood of the [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); *see also Morgan Stanley DW Inc. v. Rothe*, 150 F. Supp. 2d 67, 72-73 (D.D.C. 2001) (same). Of course, since preliminary injunctive relief is by definition provisional, "the court is not required to find that ultimate success by the movant is a mathematical probability, and indeed, the court may grant an injunction even though

its own approach may be contrary to the movants' view of the merits." *Id.* at 72 (internal quotation marks omitted).

Here, Plaintiffs have a high likelihood of prevailing on the merits and preliminary injunctive relief would prevent irreparable injury to them while leaving unharmed the interests of Defendants and the public. As discussed at length in Plaintiffs' Memorandum in Support of their Motion for Summary Judgment, the Rule constitutes a singular and unprecedented intrusion on Plaintiffs' First Amendment rights to communicate with adult customers about lawful tobacco products. FDA has failed to demonstrate that the Rule will further any government interest, much less that they are narrowly tailored to further a compelling interest. Indeed, FDA's justifications for the selected warnings find so little support in the record or reason that the Rule is arbitrary and capricious in violation of the APA.

Moreover, a short injunction postponing implementation of the new warnings and Related Requirements will harm neither FDA nor the public. The Act itself provided for a relatively lengthy rulemaking and implementation period, and FDA has demonstrated no urgency in promulgating the Rule. Presumably, this pace of rulemaking reflects the fact that the current warning and labeling regime, which has produced effectively universal awareness of the health risks of smoking, will remain fully operative until the new Rule goes into effect. Indeed, FDA itself has acknowledged that the estimated benefits from the Rule in terms of decreased smoking rates are "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776.

Fundamentally, all Plaintiffs seek is adequate time—which Congress and FDA have both recognized would be needed—to come into compliance with such new warnings and Related Requirements as this Court may hold to be required following judicial review of Plaintiffs' challenge to the Rule. Injunctive relief postponing the effective date of the new warnings and

allowing Plaintiffs to continue using their current packaging and advertising until 15 months following a decision by this Court is plainly appropriate under 5 U.S.C. § 705 and Federal Rule of Civil Procedure 65.

I. THERE IS A (MORE THAN) SUBSTANTIAL LIKELIHOOD THAT THE RULE VIOLATES THE FIRST AMENDMENT AND THE APA.

As discussed in Plaintiffs' Motion for Summary Judgment and supporting Memorandum ("SJ Mem."), the Rule violates both the First Amendment and the APA. Plaintiffs will not belabor these arguments here.

In short, the Rule violates the First Amendment under any standard of review. First, by confiscating the top 50% of both the front and back panels of Plaintiffs' cigarette packages and the top 20% of cigarette advertisements to display non-factual and highly controversial graphic warnings designed to disgust, frighten and revolt, the Rule seeks to promote the Government's anti-smoking message and to drown out plaintiffs' own speech promoting their lawful products to adult customers. The Rule is therefore subject to, and cannot survive, strict scrutiny under the First Amendment, pursuant to which it is presumptively unconstitutional. *See* SJ Mem. at 17-31; *Wooley*, 430 U.S. at 714; *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995).

Unlike normal product warnings, the graphic "warnings" required by the Rule do not fit within the limited exception to strict scrutiny that allows the Government to compel disclosure of "purely factual and uncontroversial" information. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The new graphic warnings are manifestly not "purely factual and uncontroversial." But even if they were, they would still be unconstitutional under the First Amendment because even purely factual and uncontroversial disclosure requirements cannot be "unjustified [and] unduly burdensome." *See id*. Yet FDA has conceded that the

estimated impact of the Rule on smoking rates is "in general not statistically distinguishable from zero," 76 Fed. Reg. at 36,776, and the confiscation of *half* of both sides of cigarette packaging and *one fifth* of all cigarette advertising for the Government's anti-smoking message imposes obvious and substantial burdens on Plaintiffs. It is therefore difficult to conceive of warnings that are more clearly "unjustified [and] unduly burdensome." *See* SJ Mem. at 31-35.

The Rule also unconstitutionally burdens Plaintiffs' right to engage in protected commercial speech, while failing to directly advance any legitimate governmental interest. The Rule thus fails the test applied to restrictions on commercial speech as set forth in *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980). *See* SJ Mem. at 35-37.

Were similar warnings required on other lawful products disfavored by the Government, the infringement on First Amendment rights would be readily apparent. For example, it could not seriously be suggested that the Government could require images of grossly obese individuals or bodies on autopsy tables to be displayed on fast food packages because the Government disfavors obesity, or images of diseased livers or crying children to be displayed on wine bottles to discourage adult consumption. If the Rule is constitutional, however, then so would be the warnings set forth below:

The Rule's imposition of comparable "warnings" is equally unlawful here. There is no "'vice' exception" to the First Amendment. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513-14 (1996) (plurality opinion).

Finally, in promulgating the Rule, FDA also violated the APA. FDA acted arbitrarily and capriciously by selected warnings based on reasoning that was illogical, not supported by the record, and contradictory, and ignored less intrusive but equally effective alternatives. *See* SJ Mem. at 37-41. And FDA also failed to provide sufficient notice to allow meaningful comment on the Rule. *See* SJ Mem. at 41-43.

Accordingly, there is more than a "substantial likelihood," *Davis*, 571 F.3d at 1291, that Plaintiffs will ultimately prevail in their challenge to the Rule.

II. PLAINTIFFS WILL SUFFER IRREPARABLE INJURY ABSENT PRELIMINARY RELIEF.

The new warnings and Related Requirements cannot be implemented without extensive advance preparation and expenditures. Congress and FDA recognized as much and therefore provided for a 15-month implementation period. *See* 123 Stat. 1845; *see also* 76 Fed. Reg. at 36,703 ("The Tobacco Control Act specifies a 15-month implementation period for cigarette manufacturers to include required warnings on their packages and for all cigarette advertisements to comply with this rule. We agree this is an appropriate amount of time for implementation of the rule."); *id.* at 36716 (explaining that the agency included "10 percent rush charges" in calculating the cost of the rule because "[r]esources are scarce and a large number of labeling changes [would have to be] simultaneously rushed" to meet the 15-month deadline).

It is likewise clear that Plaintiffs cannot risk disregarding the Rule until there is greater legal certainty about its validity. As a practical matter, this means that Plaintiffs cannot wait for this Court to rule on their summary judgment motion before beginning to prepare their new packaging. Therefore, unless the effective date of the new warnings is enjoined until 15 months after this Court rules on the merits of Plaintiffs' claims—the compliance period that Congress and FDA determined was necessary here—Plaintiffs will be forced to spend millions of dollars and thousands of employee-hours to comply with a regulation despite the substantial chance that the regulation is constitutionally invalid. These costs are detailed at greater length in the accompanying affidavits, but they are considerable. For example:

- Plaintiff R.J. Reynolds Tobacco ("RJRT") would be forced to modify approximately 480 distinct package designs. *See* Affidavit of J. Brice O'Brien ¶ 5.

- RJRT has therefore already purchased blank metal printing cylinders, which will be engraved and used to apply the ink on the new cigarette packaging, at a cost of $1.5 million. *Id.* ¶ 8.
- RJRT has hired a graphics design firm to design the new labeling; the firm has already begun this work, which will result in approximately $0.5 million in costs from late June through mid-December 2011. *Id.* ¶ 9.
- RJRT will soon need to begin the internal approval process for the new package designs in September 2011. The approval process will be extensive given the nature of the label changes and the number of individual designs. Numerous departments—including Consumer Marketing, Corporate Relations, Legal, Manufacturing, Operations Strategy and Innovations, Procurement, Product Services, Tax, and Trade Marketing—will need to review and approve approximately 490 individual designs. RJRT's Product Integrity team will also undertake a detailed review and approval of each pack and carton. On average, this review will require approximately 6 hours per design. *Id.* ¶ 10.
- RJRT will have to contract with its third-party design firm to engrave approximately 2,500 printing cylinders with the new packaging designs beginning in November 2011. The cost of this engraving will be approximately $3.8 million. *Id.* ¶ 11.
- RJRT will also have to order new embossing for its Pall Mall and Camel packaging in December 2011 at a cost of $0.2 million and for its Camel packaging at a cost of $0.5 million in January 2011. *Id.* ¶ 12.

- RJRT will need to provide the engraved cylinders to its third-party packaging manufacturer and contract for the production of new packaging by March 2012. The manufacturer must begin production in March because it will need to produce the new packaging while still producing RJRT's current packaging. The manufacturer will therefore not have its full manufacturing capacity available for the new packaging. The cost of producing the new packaging will be approximately $5.0 million. *Id.* ¶ 13.
- In addition to the monetary costs described above, the foregoing tasks will occupy over 4,000 hours of RJRT employee time. *Id.* ¶ 14.

Plaintiffs Lorillard Tobacco Company, Commonwealth Brands, Inc., and Liggett Group LLC, each must also bear substantial costs. *See generally* Declaration of Stephen Klepper; Declaration of Victor D. Lindsley, III; Declaration of William Melton; Declaration of Gregory A. Sulin; Declaration of David D. Depalma.

Plaintiffs will not be able to recoup these costs if (as is likely) this Court ultimately concludes that the new warnings are unconstitutional in whole or in part, or violate the APA. Where, as here, economic losses are not recoverable later through compensatory damages, courts in this circuit have regularly held that such costs constitute "irreparable injury" justifying preliminary equitable relief. *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n. 19 (D.D.C. 2010) (holding that economic injury caused by APA violation by the FDA is irreparable "because plaintiffs cannot recover money damages against FDA."); *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." (quoting *Hoffmann-Laroche Inc. v.*

Califano, 453 F. Supp. 900, 903 (D.D.C. 1978))); *Nat'l Med. Care v. Shalala*, No. 95 Civ. 0860, 1995 U.S. Dist. LEXIS 10074, at *7 (D.D.C. June 6, 1995) (granting preliminary injunction because costs of compliance with agency's interpretation of Medicare billing requirement would cause plaintiffs irreparable harm in the form of "more than 90,000 man hours of work and over $ 1 million"; moreover, "[i]f the Court eventually decides in the Plaintiffs' favor, all of these efforts will have been rendered futile"). Accordingly, absent the relief sought here, Plaintiffs will suffer irreparable harm even if the courts ultimately conclude that Plaintiffs are correct on the merits.

This is precisely the situation that 5 U.S.C. § 705 and Rule 65 are intended to prevent. As the plain text of § 705 provides, a reviewing court should "issue all necessary and appropriate process" in order to "postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" and should do so "to the extent necessary to prevent irreparable injury." 5 U.S.C. § 705 (emphasis added). Here, as explained above, "postpon[ing] the effective date" of the new warnings and preserving the status quo is "necessary to prevent irreparable injury." *Id.*

For the same reasons, the Court should also postpone the effective dates of the Related Requirements. Congress provided that the new warnings and the Related Requirements would all become effective on the same date in order to avoid manufacturers having to undergo multiple, costly packaging changes. *See* Act § 103(q)(5), 21 U.S.C. § 387c, note (stating that FDCA § 902(a)(2) would be effective "15 months after the issuance of the [Rule]"); Act § 301, 21 U.S.C. § 387t (stating that FDCA § 920(a) would be effective "15 months after the issuance of the [Rule]"). Ensuring that the new warnings and Related Requirements take effect together is therefore necessary, as a construction of the Act in light of plain congressional intent, and to

"prevent irreparable injury" and "preserve status or rights pending conclusion of the review proceedings," 5 U.S.C. § 705.

In short, Congress intended that Plaintiffs have 15 months after they knew what new warnings would be required to implement all of the Act's new cigarette labeling requirements, and that is all Plaintiffs are seeking.

III. ENJOINING THE EFFECTIVE DATE OF THE RULE WILL NOT PREJUDICE THE INTERESTS OF FDA OR THE PUBLIC.

While Plaintiffs will necessarily and indisputably incur tens of millions of dollars in unrecoverable costs if injunctive relief is not granted, FDA can show no meaningful harm to its interests or the interests of the public from such interim relief. In the first instance, it is well established that the Government's interest in a particular regulation cannot override a party's free speech rights. Rather, "the interest of the public is in the protection of plaintiffs' First Amendment rights." *Christian Knights of KKK v. District of Columbia*, 751 F. Supp. 212, 216 (D.D.C. 1990); *see also, e.g.*, *Stewart v. District of Columbia Armory Bd.*, 789 F. Supp. 402, 406 (D.D.C. 1992) ("Whatever public interest there may be in [implementing a regulation restricting banners outside RFK Stadium], the public clearly has an interest in free speech. The public interest in this case will be served by ensuring that plaintiffs' First Amendment rights are not infringed before the constitutionality of the regulation has been definitively determined."); *O'Donnell Constr. Co. v. District of Columbia*, 963 F.2d 420, 429 (D.C. Cir. 1992) (holding that "issuance of a preliminary injunction [against a constitutionally suspect affirmative action plan] would serve the public's interest in maintaining a system of laws free of unconstitutional racial classifications"). Indeed, this Court has stated categorically that "the public interest favors a preliminary injunction whenever First Amendment rights have been violated." *People for the Ethical Treatment of Animals v. Gittens*, 215 F. Supp. 2d 120, 134 (D.D.C. 2002).

Moreover, even if the Rule were held by the Court to be lawful, there would be no basis for FDA to argue that the limited delay sought in implementing the Rule would cause harm to the public interest.

First, the Act itself undermines any suggestion that the imposition of the new warnings and Related Requirements is a matter of extreme urgency. Indeed, the Act provided FDA with up to *two years* to finalize the warnings, and another 15 months before the new warnings and Related Requirements would take effect. *See supra* at 9-10. These extended timelines belie any suggestion that a short additional delay to preserve the status quo to allow meaningful judicial review will detrimentally affect the Government or the public interest.

Second, FDA has also shown no urgency in promulgating the Rule. Because the Act ties the effective date of the new warnings and Related Requirements to the publication date of the Rule, FDA could have substantially advanced the date on which these requirements would become effective by issuing the Rule promptly after the passage of the Act. However, FDA instead waited the maximum two years allowed under the Act before publishing the Rule, thus belying any claim that delaying the new warnings and the Related Requirements by a few more months would harm the public interest.

Third, a short delay would not cause any cigarettes to be sold without adequate health warnings or other labeling. Rather, the current Surgeon General's warnings will continue to be displayed on *all* cigarette packages and in *all* cigarette advertisements. Indeed, FDA itself previously *rejected* a request for more expanded warnings precisely because it concluded that "the current Surgeon General's warnings are sufficient" as a means of conveying the "'relevant warnings, precautions, side effects, and contraindications'" of cigarettes. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children

and Adolescents, 61 Fed. Reg. at 44,521 (Aug. 28, 1996) (quoting 21 U.S.C. § 352(r)). Although FDA now conclusorily asserts that the Surgeon General's warnings "fail to convey relevant information in an effective way," Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,525 (Nov. 12, 2010), it has provided no reasoned or scientific basis for this view. Moreover, available empirical evidence confirms that the Surgeon General's warnings have not only produced effectively universal awareness of the health risks of smoking, but that most consumers in fact overestimate the seriousness of the health risks associated with smoking. *See* SJ Mem. at 14-15.

Finally, as indicated above, FDA has cited no empirical evidence that the new warnings set forth in the final Rule will in fact reduce consumption or change smoking behavior. To the contrary, it has acknowledged that the opposite is true. FDA's own study concluded that the warnings imposed by the Rule will have no material effect on consumers' understanding of the risks of smoking or consumers' intentions to smoke. *See* SJ Mem. 11-14. Consistent with this finding, FDA's own analysis estimated that the Rule's impact on smoking rates would be "in general not statistically distinguishable from zero." *See* SJ Mem. 7-10. Thus, the Government's own findings suggest that the Rule would not prevent any material harm to the Government's or the public's interests even if implemented *permanently*; *a fortiori*, a short delay in the implementation of the Rule will not meaningfully affect those interests.

In short, given that Congress and FDA themselves acknowledged the propriety of a lengthy implementation period, existing warnings that FDA previously found were sufficient will continue to remain in force, and FDA itself found that the Rule will have essentially no material effect on consumers' understanding of the risks of smoking or consumers' intentions to smoke, it is clear that no substantial injury would be caused to FDA or the public by allowing Plaintiffs to

continue using their current packaging and advertising for the short period of additional time necessary to allow for meaningful review of the legality of the Rule. In contrast, absent such relief, the Rule will irreparably deprive Plaintiffs of both their First Amendment rights and the millions of dollars necessary to assure compliance under the existing effective date.

CONCLUSION

For the foregoing reasons, in accordance with 5 U.S.C. § 705 and Federal Rule of Civil Procedure 65, Plaintiffs request that this Court preliminarily enjoin the effective date of the new warnings and Related Requirements and allow Plaintiffs to continue using their current packaging and advertising until 15 months following a decision by this Court.

Respectfully Submitted,

Dated: August 19, 2011

/s/ Noel J. Francicco

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IN THE 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. 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.	Civil Action No. 11-01482 (RCL)

[PROPOSED] ORDER GRANTING PRELIMINARILY INJUNCTIVE RELIEF

The Court having determined that Plaintiffs have demonstrated a substantial likelihood of success on the merits, that Plaintiffs would suffer irreparable injury absent this order, and that neither the Defendant nor the Public would suffer comparable injury from this order,

IT IS HEREBY ORDERED that Plaintiffs' Motion For Preliminary Injunction is GRANTED. Pursuant to 5 U.S.C. § 705 and Rule 65 of the Federal Rules of Civil Procedure, the Court hereby ORDERS:

1. Defendants are enjoined from enforcing against Plaintiffs in this case, until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims, the effective date of the new textual and graphic warnings implemented by the regulation published at 76 Fed. Reg. 36,628 (June 22, 2011) and by Section 201(a) of the Tobacco Control Act.

2. Defendants are enjoined from enforcing against Plaintiffs in this case, until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims, the effective date of the following statutory provisions, which impose the stated labeling requirements:

   a. "the name and place of business of the tobacco product manufacturer, packer, or distributor," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(A)), 21 U.S.C. § 387c(a)(2)(A);

   b. "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(B)), 21 U.S.C. § 387c(a)(2)(B);

   c. "an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco," *see* Act § 101(b) (inserting FDCA § 903(a)(2)(C)), 21 U.S.C. § 387c(a)(2)(C); and

   d. where applicable, "the statement 'Sale only allowed in the United States,'" *see* Act § 301, FDCA § 920(a), 21 U.S.C. § 387t(a).

3. Plaintiffs in this case are permitted to continue using their current cigarette packaging and advertising until 15 months after a Final Judgment from this Court addressing Plaintiffs' claims.

It is SO ORDERED this _____ day of _____, 2011.

_____
Hon. Richard J. Leon
United States District Judge