IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY,
401 North Main Street,
Winston-Salem, NC 27101
LORILLARD TOBACCO COMPANY,
714 Green Valley Road,
Greensboro, NC 27408
COMMONWEALTH BRANDS, INC.,
900 Church Street
Bowling Green, KY 42101
LIGGETT GROUP LLC,
100 Maple Lane
Mebane, NC 27302,
SANTA FE NATURAL TOBACCO COMPANY, INC.,
1 Plaza La Prensa
Santa Fe, NM 87507

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

CIVIL ACTION NO._____

COMPLAINT

I. INTRODUCTION

1. For more than 45 years, cigarettes sold in the United States have been accompanied by various Surgeon General's Warnings, and Plaintiffs have never brought a legal challenge to any of them. On June 22, 2011, however, the Food and Drug Administration ("FDA") published a final regulation specifying nine new graphic "warnings" pursuant to the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (the "Tobacco Control Act" or the "Act"), which go far beyond anything in the prior warnings. *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) (to be codified at 21 C.F.R. Part 1141) ("the Rule").

2. The Rule requires the use of nine new textual warnings, accompanied by nine graphic images—such as images of a body on an autopsy table and of diseased body parts—that are designed to shock, disgust, and frighten adult consumers of cigarettes. Under the Rule, those images must be printed in color and displayed on the top 50% of both the front and back panels of all cigarette packages and on the top 20% of all printed cigarette advertising. Moreover, through inclusion of a smoking cessation hotline, every warning must contain a direct exhortation to smokers to "QUIT-NOW." Rather than providing uncontroversial factual information to allow consumers to make an educated decision about whether to use tobacco products, the "warnings" cross the line into governmental anti-smoking advocacy.

3. Such "warnings" are unprecedented. Never before in the United States have producers of a lawful product been required to use their own packaging and advertising to convey an emotionally-charged government message urging adult consumers to shun their products. These requirements force Plaintiffs, not to convey purely factual and uncontroversial

statements about the risks of tobacco use, but rather to become a mouthpiece for the Government's emotionally-charged anti-smoking message. Indeed, FDA effectively concedes that the graphic "warnings" were selected, not to inform consumers of facts that they do not know, but rather to make consumers "depressed, discouraged, and afraid" to buy tobacco products, 76 Fed. Reg. at 36,638 (internal quotation marks omitted), in order to "motivate positive behavior change," *id.* at 36,652. As FDA Commissioner Hamburg accurately acknowledged when unveiling the proposed rule, the warnings are intended to ensure that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's anti-smoking message.[1] Or, as HHS Secretary Sebelius phrased it, the warnings effectively "rebrand[] our cigarette packs."[2]

4. This is precisely the type of compelled speech that the First Amendment prohibits. While the Government may require Plaintiffs to provide purely factual and uncontroversial information to inform consumers about the risks of tobacco products, it may not require Plaintiffs to advocate against the purchase of their own lawful products. As the Supreme Court explained in language directly applicable to this case, the First Amendment prohibits the Government from compelling individuals or corporations to "use their private property as a 'mobile billboard' for the State's ideological message." *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). Nor may the Government attempt to displace or drown out commercial speech regarding lawful products that it finds objectionable. As the Supreme Court recently held in *Sorrell v. IMS Health, Inc.*, __ S. Ct. __, 2011 WL 2472796, at *17 (June 23, 2011), "[t]he State can express

[1] FDA, *Tobacco Control Announcement* (Nov. 10, 2010), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm.

[2] 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.

[its] view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction."

5. Because the Rule compels Plaintiffs to engage in anti-smoking advocacy on behalf of the Government, it is subject to strict scrutiny, a standard that the Government cannot possibly satisfy. Indeed, because FDA's own findings indicate that the warnings will not provide *any* new information to consumers or have *any* material impact on smoking prevalence, and because the Rule has an impermissible purpose and effect of burdening Plaintiffs' efforts to promote their lawful products, it violates the First Amendment under any standard of review.

6. Finally, the Rule also contravenes core requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*

7. In light of the foregoing, the Rule is invalid as applied to Plaintiffs and, therefore, the Court should permanently enjoin FDA from enforcing it.

II. PARTIES

8. Plaintiff R.J. Reynolds Tobacco Company ("RJRT") is a North Carolina corporation with its corporate offices and manufacturing operations located in Winston-Salem, North Carolina. RJRT is the second-largest tobacco manufacturer in the United States. Its cigarette brands are sold under the brand names Camel, Winston, Kool, and Pall Mall, among others. RJRT's brands are advertised, distributed, and sold nationwide, including in this district. RJRT is a signatory to the 1998 Master Settlement Agreement ("MSA") as an Original Participating Manufacturer ("OPM").

9. Plaintiff Lorillard Tobacco Company ("Lorillard") is a Delaware corporation with its corporate offices and manufacturing operations located in Greensboro, North Carolina. Lorillard is the third-largest tobacco manufacturer in the United States, selling a variety of cigarette brands. Its cigarette brands are sold under the brand names Newport, Maverick, True, and Old Gold, among others. Lorillard's brands are advertised, distributed, and sold nationwide, including in this district. Lorillard is a signatory to the MSA as an OPM.

10. Plaintiff Commonwealth Brands, Inc. ("Commonwealth") is a Kentucky corporation with its corporate offices located in Bowling Green, Warren County, Kentucky, and its manufacturing operations in North Carolina. Commonwealth is the fourth-largest tobacco manufacturer in the United States, selling a variety of tobacco products, including cigarettes, roll-your-own tobacco, and tobacco-related products. Its cigarette brands are sold under the brand names USA Gold, Davidoff, and Sonoma, among others. Commonwealth's brands are advertised, distributed, and sold nationwide, including in this district. Commonwealth is a signatory to the MSA, as a Subsequent Participating Manufacturer ("SPM").

11. Plaintiff Liggett Group LLC ("Liggett Group") is a Delaware limited liability company with its corporate offices and manufacturing located in Mebane, North Carolina. Liggett is the fifth largest manufacturer of cigarettes in the United States in terms of unit sales. Its brands include Eve, Grand Prix, Liggett Select, and Pyramid. Liggett Group's brands are advertised, distributed, and sold nationwide, including in this district. Liggett Group is a signatory to the MSA as an SPM.

12. Plaintiff Santa Fe Natural Tobacco Company, Inc. ("SFNTC") is a New Mexico corporation with its corporate offices located in Santa Fe, New Mexico, and its manufacturing

operations in North Carolina. SFNTC is a tobacco manufacturer in the United States and sells cigarettes and roll-your-own tobacco under the Natural American Spirit brand name. SFNTC's brand is advertised, distributed, and sold nationwide, including in this district. SFNTC is a signatory to the MSA as an SPM.

13. Defendant the United States Food and Drug Administration ("FDA") is a federal agency of the United States, within the United States Department of Health and Human Services ("HHS"). Under the Tobacco Control Act and the Food Drug and Cosmetic Act ("FDCA"), the FDA is responsible for regulating tobacco products marketed in the United States. The FDA's headquarters are located in Silver Spring, Maryland. The FDA's powers and responsibilities under the Act are delegated to it through HHS Secretary Kathleen Sebelius.

14. Defendant Dr. Margaret Hamburg is the Commissioner of the FDA. Commissioner Hamburg oversees the implementation and day-to-day enforcement of the Rule.

15. Defendant Kathleen Sebelius is the Secretary of HHS, the parent agency of the FDA. Secretary Sebelius ("Secretary") oversees FDA's activities and is responsible for the implementation and enforcement of the Rule.

III. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331, 28 USC § 2201, and 5 U.S.C. § 701 *et seq*.

17. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

18. An actual controversy presently exists between the parties concerning the constitutionality and legality of the Rule. That controversy is justiciable in character, and speedy relief is necessary to preserve Plaintiffs' rights.

19. A declaratory judgment will terminate the uncertainty and controversy between the parties.

20. An injunction invalidating the Rule and prohibiting Defendants from taking any action to enforce it will protect Plaintiffs' rights.

IV. FACTUAL ALLEGATIONS

21. Even before passage of the Tobacco Control Act, Plaintiffs' ability to market their lawful products was subject to numerous restrictions. For example, federal law already prohibited Plaintiffs from advertising cigarettes in television and radio advertisements, *see* 15 U.S.C. §§ 1335, 4402, the media best suited to reaching the greatest numbers of consumers. In addition, since November 1998, numerous cigarette manufacturers, including Plaintiffs, and numerous state Attorneys General have entered into the MSA, which imposes a variety of additional restrictions and limitations on the marketing and promotion of cigarettes, including, for example, bans on outdoor and transit advertising, the acquisition of stadium or arena naming rights, and the purchase of product placement in media. *See* MSA § III. And for decades, government-mandated warnings have appeared on all cigarette packages and advertising. *See* 15 U.S.C. § 1333 (2008). These warnings have been a key part of a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health," the express purpose of which was to ensure that the public is "adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices

on each package of cigarettes and in each advertisement of cigarettes." *Id.* § 1331. The Tobacco Control Act imposes yet further marketing restrictions, including, for example, a ban on almost all color and imagery in almost all tobacco products. *See infra* ¶¶ 24-35**.**

22. As a result of these and other restrictions, even prior to the Rule, Plaintiffs' remaining avenues of communication with adult consumers were severely limited.

23. The Rule further impairs these few remaining avenues that Plaintiffs have for communicating with adult consumers by commandeering the top 50% of the front and back of Plaintiffs' packaging, and the top 20% of their advertising, to disseminate graphic anti-smoking messages crafted by the Government.

A. THE TOBACCO CONTROL ACT

24. The Rule was promulgated pursuant to the Tobacco Control Act, which imposes a sweeping set of additional restrictions on the speech of cigarette manufacturers.[3]

25. The Act restricts (subject to extremely limited exceptions) cigarette advertising to black text on a white background. *See* 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.32(a). In

[3] Plaintiffs R.J. Reynolds Tobacco, Lorillard, and Commonwealth Brands, together with other tobacco product manufacturers and retailers, have challenged various speech restrictions mandated by the Tobacco Control Act, including a facial challenge to the warnings as mandated by the Act itself. Plaintiffs Liggett Group and SFNTC were not parties to that action. The United States District Court for the Western District of Kentucky held invalid the Act's ban on color and imagery in tobacco advertising and one other provision, and upheld the new warnings and several other provisions. *See Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010). Both sides have appealed that set of rulings to the United States Court of Appeals for the Sixth Circuit. *See Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235.

The plaintiffs in *Commonwealth Brands* have argued that the Act's general graphic warnings requirement is facially unconstitutional. The *Commonwealth Brands* plaintiffs, however, did not raise the claim brought by Plaintiffs in this action—that the particular warnings required by the Rule are unconstitutional—because the Rule had not yet been promulgated at the time that case was filed. As FDA explained, although "manufacturers have known this rule was coming, in some form, since the passage of the [Act], it is only with the publication of the final rule that they . . . [knew] its exact form." 76 Fed. Reg. at 36,716. The present lawsuit challenges the specific warnings promulgated by the Rule in "its exact form." Accordingly, it turns primarily on facts not available, litigated, or considered in the *Commonwealth Brands* case.

particular, "each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any . . . advertising for cigarettes . . . shall use only black text on a white background." 21 C.F.R. § 1140.32(a). The only two exceptions are for advertisements: (1) in magazines with (a) under-18 readership of less than 15%, *and* (b) less than 2 million youth readers overall, *but only* if (c) those demographics are established by "competent and reliable survey evidence," *id.* § 1140.32(a)(2); or (2) in retail establishments if (a) the retailer "ensures" that no under-18 person "is present, or permitted to enter, at any time," *and* (b) the advertisement is "affixed to a wall or fixture in the facility," *and* (c) it is not "visible from outside the facility," *id.* §§ 1140.16(c)(2)(ii), 1140.32(a)(1). As a result, color and imagery—including Plaintiffs' well-known and valuable trademarks—are effectively banned from 100% of direct mail advertising, 99% of advertising at retail points of sale, and 99% of all magazine advertising.

26. The Act also contains numerous other restrictions on Plaintiffs' commercial speech. In particular, it:

a. bans Plaintiffs from sponsoring "any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name . . . , logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes," 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(c);

b. bars Plaintiffs from marketing, distributing, or selling any promotional item (such as hats and t-shirts) bearing the "brand name . . . , logo,

symbol, motto, selling message, [or] recognizable color or pattern of colors" of any cigarette brand, 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(a);

c. prevents Plaintiffs from "distribut[ing] or caus[ing] to be distributed free samples of cigarettes," 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d);

d. prohibits Plaintiffs from engaging in promotions that offer "any gift or item" in consideration of the purchase of cigarettes or "to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase," 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(b);

e. restricts Plaintiffs from marketing cigarettes "in combination with any other article or product regulated" by FDA, 21 U.S.C. § 321(rr)(4); and

f. provides that federal agencies, states or subdivisions, or Indian tribes may "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than" those of the Act, including with respect to "advertising and promotion," 21 U.S.C. § 387p, and that states or localities may enact statutes and promulgate regulations that impose "specific bans or restrictions on the time, place, and manner, but not content," of cigarette advertising and promotion, Pub. L. No. 111-31, § 203 (adding 15 U.S.C. § 1334(c)).

27. The Act also directs FDA to promulgate: either (1) an outdoor advertising ban that prohibits all "outdoor advertising for cigarettes . . . , including billboards, posters, or placards, . . . within 1,000 feet of the perimeter of any public playground or playground area in a public park . . . , elementary school, or secondary school," or (2) a modified version of this ban which shall then become effective without regard to the requirements of the APA. 21 U.S.C. § 387a-1(a)(1), (a)(2)(E); 21 C.F.R. § 897.30(b) (1996). On March 19, 2010, FDA solicited comments about how it should promulgate such a regulation consistent with the First Amendment. *See* Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act, 75 Fed. Reg. 13,241 (Mar. 19, 2010) (to be codified at 21 C.F.R. Part 1140).

28. Finally, the Act directs the Secretary to issue regulations seizing a substantial portion of Plaintiffs' packaging and printed advertising for a government-drafted graphic anti-tobacco message. Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333).

29. In particular, the Act requires FDA to issue regulations seizing "the top 50 percent of the front and rear panels of" a package of cigarettes for one of nine specified "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.

Id.

30. The textual warnings, which are to be rotated on packaging under a plan approved by FDA, are to appear "in conspicuous and legible 17-point type . . . . in a manner that contrasts, by typography, layout, or color, with all other printed material on the package." *Id.*

31. The warnings, moreover, must include "color graphics depicting the negative health consequences of smoking." *Id.* (amending 15 U.S.C. § 1333(d)).

32. Identical graphic warnings must appear on the top 20 percent of any printed advertisement. *Id.* (amending 15 U.S.C. § 1333(b), (d)).

33. The Act required FDA to issue regulations implementing these requirements "[n]ot later than 24 months after the date of enactment of the [Act]." Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333(d)). In light of the Act's enactment on June 22, 2009, the regulations were therefore required to be issued not later than June 22, 2011.

34. The Act also requires cigarette packaging to include other detailed information (the "Related Requirements"), including:

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).

35. The Act provides that the new textual and graphic warnings and each of the Related Requirements will become effective "15 months after the issuance of" the Rule. 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")); *see also* Act § 103(q)(5), 21 U.S.C. § 387c, note (using identical text to set the effective date for the Related Requirements of FDCA § 902(a)(2)(A)-(C)); Act § 301, 21 U.S.C. § 387t (using identical text to set the effective date for the Related Requirement of FDCA § 920(a)). 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.

B. FDA'S PROPOSED RULE

36. On November 12, 2010, FDA issued a Proposed Rule identifying a selection of proposed graphic images and implementing the Act's related warning provisions. *See* Required

Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524 (Nov. 12, 2010) (to be codified at 21 C.F.R. Part 1141).

37. The Proposed Rule required tobacco companies to use the top 50% of both the front and back panels of their cigarette packages and the top 20% of cigarette advertisements to present graphic warnings regarding the health consequences of smoking. *Id.* at 69,563 (proposing 21 C.F.R. § 1141.10(a)(4)).

38. The Proposed Rule selected four graphic images to be paired with each of the Act's nine new textual warnings, for a total of 36 proposed graphic warnings. These proposed images were controversial and non-factual. They were to appear in color and they included cartoon images, as well as disturbing, technologically enhanced photographs that used actors to maximize an emotional response from viewers. A copy of these images can be found at http://www.fda.gov/downloads/TobaccoProducts/Labeling/CigaretteProduct WarningLabels/UCM232425.pdf.

39. The Proposed Rule also required cigarette packaging and advertising to include a "reference to a smoking cessation assistance resource in accordance with, and as specified in, 'Cigarette Required Warnings—English and Spanish' (incorporated by reference at § 1141.12) or 'Cigarette Required Warnings—Other Foreign Language Advertisements' (incorporated by reference at § 1141.12), whichever is applicable." 75 Fed. Reg. at 69,564 (proposing 21 C.F.R. § 1141.16(a)). The Proposed Rule set forth several vague requirements for such a "smoking cessation assistance resource." For example, such a resource would have to: provide "evidence-based advice" about how to quit smoking; provide "evidence-based information about effective relapse prevention strategies"; provide "information, advice, and support that is evidence-based,

unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation"; not "selectively present information about a subset of FDA-approved cessation products or product categories"; and "[n]ot encourage the use of any non-evidence-based smoking cessation practices." *Id.* (proposing 21 C.F.R. § 1141.16(b)). The Proposed Rule did not identify any existing "cessation assistance resource." *Id.*

C. FDA'S REGULATORY IMPACT ANALYSIS

40. The Proposed Rule included FDA's regulatory impact analysis ("RIA"), which analyzed the benefits and costs of the Proposed Rule.

41. The potential benefits described in the RIA were based on FDA's speculation that the new warnings might reduce smoking prevalence. In so speculating, the RIA made the following two assumptions: (1) after Canada introduced similar graphic warnings in 2000, any reduction in Canadian smoking rate trends beyond those that occurred in the United States over the same period were caused by the new graphic warnings as opposed to other factors; and (2) the Rule would cause the same change in U.S. smoking rates. As FDA acknowledged, however, "[i]mplicit in this method is the assumption that these otherwise unexplained differences may be attributed solely to the presence in Canada of graphic warning labels." 75 Fed. Reg. at 69,453. FDA further conceded that its failure to account for other "confounding factors" rendered its estimate highly uncertain, acknowledging that "the U.S. social and policy climate may have been so different from Canada's during the year's 1999-2008 that this proxy is inappropriate." *Id.* at 69456. Based on this analysis, FDA estimated that the Proposed Rule would reduce U.S. smoking rates by 0.212%. *Id.* at 69,543. However, FDA conceded that this estimated reduction

in smoking rates was, in actuality, "*not statistically distinguishable from zero*." *Id.* at 69,546 (emphasis added).

42. The RIA's benefits analysis, moreover, suffers from at least two fatal flaws, both of which biased the analysis in favor of overstating benefits from the Proposed Rule.

43. First, there is no evidence that the introduction of graphic warnings in Canada caused any decrease in Canadian smoking rates. From 1985 to present, smoking rates have consistently declined in Canada. As a result, the appropriate test for the effect of the introduction of graphic warnings in Canada in 2000 is whether the new warnings caused an acceleration of the pre-existing downward trend. In fact, as the administrative record demonstrates, there has been no such shift.[4] Viscusi Report at 80 ("In the case of Canada, which uses both large text, placed on the front and back of the pack, and graphic imagery regarding health effects of smoking, there is no apparent impact at all on the trend in smoking prevalence."); Maness Report at 7 (noting that FDA did "not appear to conduct any statistical tests of whether the trend after 2000 is in any way different from the trend from 1985 to 2000").

44. Second, there are numerous "confounding factors," other than the presence or absence of graphic warnings, that are unique to Canada and could explain the differences between Canadian and U.S. smoking rates. Maness Report at 12-21. For example, since the introduction of graphic warnings in Canada, cigarette prices have increased in that country at nearly twice the rate of prices in the United States. Because price increases have a well-demonstrated impact on smoking prevalence, this factor alone may "explain all or some of any

[4] *See* Comment Letter of R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, and Commonwealth Brands, Inc., Docket No. FDA-2010-N-0568-0658 (Jan. 11, 2011) ("Comment Letter"), Exhibit A, Statement of W. Kip Viscusi ("Viscusi Report") & Exhibit B, Statement of Robert S. Maness ("Maness Report").

resulting divergence in rates of change of smoking prevalence across the two countries." *Id.* at 12. In addition, Canada's population has aged more rapidly than the population of the United States, which also causes Canada to have lower overall smoking rates because smoking prevalence is lower in the over-65 population. *Id.* at 18-19. And unlike in the United States, since 2002, eight of Canada's 13 provinces and territories have outright banned all retail displays of tobacco products, and another four have banned such displays in retail establishments open to minors. *Id.* at 18. In purportedly analyzing the potential benefits of the Proposed Rule, however, FDA controlled for *none* of these factors.

45. Notwithstanding these flaws, which led FDA to overstate the benefits of the proposed warnings, the RIA *still* concluded that the estimated impact of the proposed warnings on smoking rates was "not statistically distinguishable from zero." 75 Fed. Reg. at 69,546.

46. The RIA similarly understates the costs of the proposed warnings. For example, while FDA counted as benefits of the new warnings all healthcare savings achieved by reductions in smoking rates, it ignored the healthcare, social security, and other cost *increases* caused by increased longevity. Viscusi Report at 88; Maness Report at 20-21. Although the costs associated with increased longevity are obviously desirable, they are nonetheless costs that must be accounted for in any cost-benefit analysis. FDA likewise ignored or understated numerous other costs, such as: the competitive disadvantage that the Proposed Rule would impose on premium branded cigarettes compared to generic cigarettes, which would in turn exert downward pressure on cigarettes prices and, hence, upward pressure on cigarette use, Maness Report at 24; the costs of reduced cigarette consumption in the form of lost income for tobacco growers, lost jobs in cigarette manufacturing, and lost profits for retailers, which FDA dismissed

as mere "distributional effects," *id.* at 27-31; and numerous other costs that the Proposed Rule would likely cause.

D. THE FDA-SPONSORED STUDY

47. The Proposed Rule was also based on an experimental study commissioned by FDA to assess the effectiveness of the proposed graphic warnings. The FDA Study tested whether each of the 36 graphic warnings contained in the Proposed Rule would be effective in accomplishing any of three goals: (1) increasing awareness among adults, young adults, and youth about the health risks from smoking, including the risks from "environmental tobacco smoke" ("ETS" or "second-hand smoke"); (2) increasing current adult and young adult smokers' intention to quit; and (3) decreasing youth non-smokers' likelihood to initiate smoking.

48. Even if taken at face value, the FDA Study demonstrated that *none* of the 36 graphic warnings were effective across all three of the variables measured, and the vast majority of them had *no* statistically significant effect on beliefs about the health risks from smoking and second-hand smoke, smokers' intentions to quit, or youth initiation of smoking. Indeed, "[s]everal of the proposed new graphic warning statements were negatively associated with beliefs regarding the risk[s] of smoking." Viscusi Report at 61.

49. Moreover, the FDA Study found the proposed warnings to be ineffective notwithstanding serious methodological flaws designed to overstate the effectiveness of the graphic warnings. For example, the FDA Study treated participants' statements as to whether they *intended* to take action based on a particular warning as a reliable indicator of whether they would in fact quit or refrain from using cigarettes in response to the new warnings. But "[q]uestions that ask respondents whether they will engage in activity that is either illegal

(among the minor respondents) or socially undesirable (smoking), may be biased by the likely desire of respondents to offer the legal and/or socially desirable response." *Id.* at 45. "Consequently, quit intentions such as this tend to *significantly overestimate* the number of smokers who actually intend to quit as a result of the proposed warning." *Id.* at 63. Dr. Viscusi's analysis documents numerous other similar methodological flaws.

50. As Dr. Viscusi explains, the reason why the Proposed Rule had no material impact on smoking beliefs and behavior, and why the Rule likewise will likely have no material impact, is because the factual health information in each of the proposed warnings has already been "disseminated to and absorbed by an overwhelmingly high percentage of the population" through the familiar Surgeon General's warnings and numerous other means. *Id.* at 15.

51. For example, more people are aware of the health risks of smoking than "are aware that George Washington was the first U.S. President, [or] that the Earth revolves around the Sun." *Id.* at 10. Indeed, the public actually *overestimates* the risks from tobacco use by as much as 400%: "[T]he average perceived risk that a smoker will develop lung cancer is over 40%," whereas the "actual risk" is "about 10% of smokers." *Id.* at 25. Similarly, the public's perception of the overall mortality risk from smoking "can be as much as three times higher" than the actual mortality risk, and "young people overestimate the dangers of smoking to an even greater degree" than adults. *Id.* at 28-29.

52. "Independent studies," therefore, "have demonstrated that more information about the risks of smoking does not influence smoking rates or consumer behavior." *Id.* at 21.

53. For example, a 1994 report by the Surgeon General acknowledged the inaccuracy of the "'assumption . . . [that] young people had a deficit of information that could be addressed

by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke.'" *Id.* at 68. As the Surgeon General explained:

> In the 1960s and early 1970s, strategies to prevent the onset of cigarette smoking were often based on the premise that adolescents who engaged in smoking behavior had failed to comprehend the Surgeon General's warnings on the health hazards of smoking. The assumption was that these young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke. (citation omitted)
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> Comprehensive reviews published at that time concluded that smoking-prevention programs based on the information deficit approach were not effective.

Id.

54. In light of the RIA, the FDA Study, the Viscusi Report, and the Maness Report, FDA could not demonstrate that the benefits of the Proposed Rule outweighed its costs, much less that they *significantly* outweighed the costs. To the contrary, the Proposed Rule's costs, including the burdens imposed on Plaintiffs' speech, clearly outweighed the Proposed Rule's benefits.

E. COMMENTS TO FDA

55. On January 11, 2011, Plaintiffs R.J. Reynolds Tobacco, Lorillard, and Commonwealth Brands submitted to FDA their extensive Comment Letter on the Proposed Rule, *see supra* ¶ 43, note 4, which identified numerous flaws in the Proposed Rule, including the following:

a. *First*, Plaintiffs noted that the Proposed Rule's graphic warnings were not purely factual and non-controversial commercial disclosures and, as a result, were subject to strict scrutiny under the First Amendment, a standard that the warnings could not remotely satisfy. *See, e.g.*, *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995); *Wooley*, 430 U.S. at 715.

b. *Second*, Plaintiffs emphasized that the Proposed Rule's graphic warnings would fail even the lesser standard of scrutiny applicable to purely factual and uncontroversial disclosures aimed at preventing consumer deception. Specifically, in light of the FDA's own findings that the warnings would have no meaningful effect, as well as the Viscusi and Maness Reports, the warnings were not possibly consistent with the prohibition on factual commercial disclosures that are "unjustified and unduly burdensome." *See, e.g.*, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

c. *Third*, Plaintiffs argued that, because the graphic warnings not only compelled them to disseminate the Government's message, but also burdened Plaintiffs' own speech, the Proposed Rule was subject to, and would fail, the scrutiny for commercial speech restrictions set forth in *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980).

d. *Fourth*, Plaintiffs described numerous alternatives to the Proposed Rule that would be no less effective than the proposed graphic warnings, but would impose fewer burdens on Plaintiffs' constitutional rights and legitimate business interests, thus rendering the Proposed Rule arbitrary and capricious under the APA. *See* 5 U.S.C. § 706(2)(A).

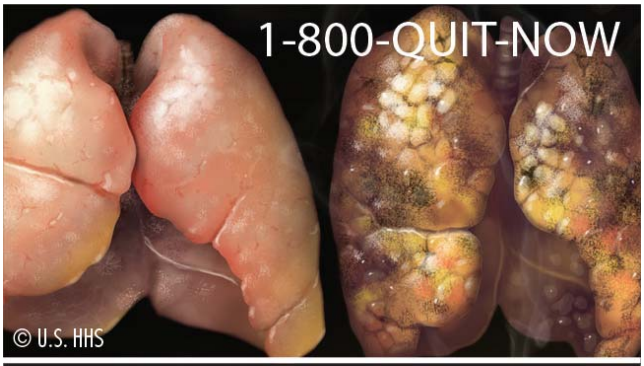
e. *Fifth*, Plaintiffs pointed out that the Proposed Rule also violated the Administrative Procedure Act ("APA") because FDA had failed to disclose key technical information regarding the studies, assumptions, and methodologies on which it had relied in formulating the Proposed Rule, thereby depriving Plaintiffs of an adequate opportunity to comment on the Proposed Rule. 5 U.S.C. § 553(b)(3).

56. Other manufacturers and interested parties raised similar objections. For example, Philip Morris USA Inc. submitted comments noting that the warnings required by the Proposed Rule violated the First Amendment. Philip Morris Comment Letter, Docket No. FDA-2010-N-0568-0669 (Jan. 11, 2011). Likewise, the Association of National Advertisers, Inc. and the American Advertising Federation (the "Advertising Associations") also submitted comments emphasizing that the Proposed Rule "ignore[d] constitutional protections afforded advertising and product packaging, at the expense of core First Amendment principles." Advertising Associations Comment Letter 1, Docket No. FDA-2010-N-0568-0063 (Jan. 11, 2011).

F. FDA'S FINAL RULE

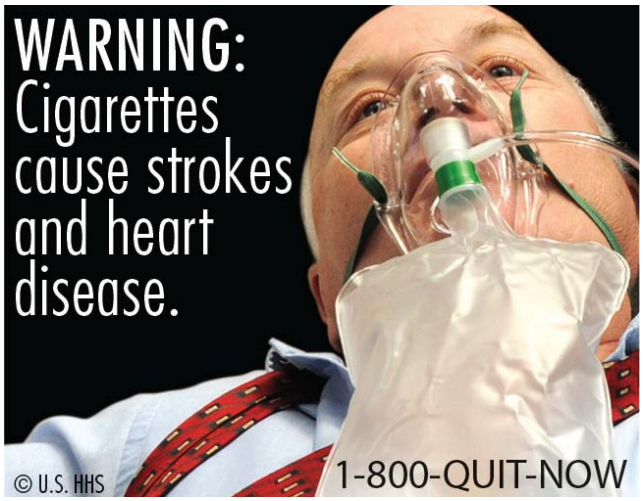
57. Despite being advised of the foregoing flaws, FDA promulgated the Rule on June 22, 2011, without making any meaningful changes to the Proposed Rule. In particular, the Rule

imposes a selection of nine of the 36 warnings contained in the Proposed Rule and requires that they be displayed in the same manner, all without modifying FDA's prior findings that such warnings will have no effect on consumer understanding, smoking intentions, or smoking decisions. Likewise, the Rule fails to remedy the lack of meaningful notice provided in the Proposed Rule or provide any rational basis for rejecting less burdensome alternatives to the required warnings. In particular, the Rule adopts the following nine graphic warnings:



WARNING: Cigarettes cause fatal lung disease.

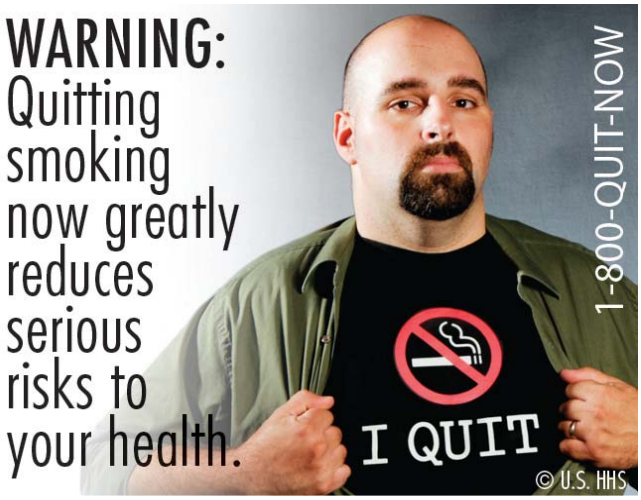
WARNING: Cigarettes cause cancer.




WARNING: SMOKING DURING PREGNANCY CAN HARM YOUR BABY.
1-800-QUIT-NOW
© U.S. HHS


© U.S. HHS
1-800-QUIT-NOW
WARNING:
Smoking can kill you.


WARNING:
Tobacco smoke
causes fatal
lung disease
in nonsmokers.
1-800-QUIT-NOW
© U.S. HHS



58. In selecting these warnings from the set of 36 proposed warnings, FDA relied primarily on the warnings' performance on "salience" measures in the FDA Study. *See* 76 Fed. Reg. at 36,639. Those salience measures did not measure the impact of the warnings on consumer awareness of smoking risks or quit intentions. Instead, the salience measures assessed the warnings' emotional impact—whether they made viewers "depressed, discouraged, and afraid," or were described with terms such as "convincing" or "difficult to look at." *Id.* at 36,638 (internal quotation marks omitted).

59. The warnings required by the Rule include emotionally-charged graphics that employ cartoons, actors, and/or technological manipulations. These manipulations exaggerate the potential effects of smoking. For example:

a. The "Hole in Throat" graphic is a photoshopped illustration that employs technological manipulation. This manipulation exaggerates the disturbing effect of smoking through a tracheotomy hole.

b. Upon information and belief, the “Smoke Approaching Baby” employs actors and technological manipulation to create a stylized plume of smoke approaching a baby.

c. Upon information and belief, the “Healthy/Diseased Lungs” graphic uses animation and/or technological manipulation. This animation and/or manipulation sanitizes an image of a healthy lung and emphasizes the grotesque appearance of a diseased lung.

d. Upon information and belief, the “Cancerous Lesion on Lip” graphic employs technological manipulation. This manipulation exaggerates the disturbing appearance of discolored teeth and a lip lesion.

e. Upon information and belief, the “Man with Oxygen Mask” graphic employs an actor apparently to depict an individual suffering from some sort of respiratory ailment.

f. The “Baby in Incubator” graphic employs animation. This animation creates a stylized portrayal of an infant suffering.

g. The “Man with Chest Staples” graphic employs an actor and a fake autopsy scar. These effects exaggerate the grotesque appearance of victims of smoking-related disease. The exaggeration in this case is particularly unrealistic because victims of smoking related disease are not typically given autopsies.

h. The "Man with T-shirt" graphic employs an actor wearing a t-shirt depicting the universal "no smoking" symbol and the declaration "I QUIT."

60. The Rule also requires all warnings to display the following telephone number of a smoking cessation resource: "1-800-QUIT-NOW." 76 Fed. Reg. at 36,754-55.

61. The FDA Study shows that the nine graphic warnings required by the Rule have no effect on consumer understanding of smoking risks, consumer attitudes toward smoking, or consumer smoking decisions:

a. *Hole in Throat:* This warning had no effect on the reported smoking intentions of adults, young adults, or youth and no effect on awareness of smoking or ETS risks among young adults or youth. Although the warning did show a correlation with adults' awareness of smoking and ETS risks when viewed on a cigarette package, the fact that the warning had no effect on adults' awareness of smoking risks when the warning was viewed as part of an advertisement and that the warning has nothing to do with ETS risks suggests that any effect on consumers is emotional rather than informational. *See* Viscusi Report at 70.

b. *Smoke Approaching Baby:* Although this warning did have some effect on reported intentions to initiate smoking among youth, it had no effect on adult, young adult, or youth awareness of smoking risks or ETS risks; and it had no effect on the quit intentions of adults or young adults. *Id.*

c. *Healthy/Diseased Lungs:* This warning had no effect across *any* of the relevant study metrics. It did not affect adult, young adult, or youth awareness of smoking risks; it

did not affect adult, young adult, or youth awareness of ETS risks; it did not affect the quit intentions of adults or young adults; and it did not affect youth intentions to initiate smoking. *Id.* at 71.

d. *Cancerous Lesion on Lip:* This warning likewise had no effect across *any* of the relevant study metrics.

e. *Oxygen Mask on Man's Face:* This warning likewise had no effect across *any* of the relevant study metrics.

f. *Baby in Incubator:* This warning had no effect on young adult awareness of smoking risks; no effect on adult, young adult, or youth awareness of ETS risks; no effect on the quit intentions of adults or young adults; and no effect on youth intentions to initiate smoking. While this warning showed a correlation with increased awareness of smoking risks among adults, it was also correlated with a *decreased* awareness of smoking risks among youth. *Id.* at 72.

g. *Man with Chest Staples:* This warning had no impact on any demographic group's awareness of smoking or ETS risks. Moreover, while the warning was associated with an increase in adult quit intentions, it had no impact on young adult quit intentions or youth intentions to initiate smoking. *Id.*

h. *Woman Crying:* This warning had no impact on any demographic group's awareness of smoking or ETS risks. Moreover, while the warning was associated with an increase in young adult quit intentions, it had no impact on adult quit intentions or youth intentions to initiate smoking. *Id.*

i. *Man I Quit T-Shirt:* This warning had no effect across *any* of the study metrics.

62. The RIA in the Rule follows the same approach as the Proposed Rule, except that it accounts for a single confounding factor: the differential in Canadian and U.S. cigarette tax rates. 76 Fed. Reg. at 36,711. In adjusting for this single factor, the RIA's estimated (but statistically insignificant) reduction in smoking rates attributable to the warnings fell from 0.212% to 0.088%. *Id.* at 36,721. FDA continues to acknowledge that its RIA does "not account for [any other] potential confounding variables," *id.* at 36,720, and that its estimate of the decline in the U.S. smoking rate attributable to the warnings is "*in general not statistically distinguishable from zero*," *id*. at 36,776 (emphasis added).

63. The methodology reflected in the Rule, moreover, suffers from the same numerous flaws in the RIA and FDA Study, discussed above, which biased the agency's analysis toward finding that the Rule might have meaningful benefits. *See supra* at ¶¶ 40-54

64. Likewise, the agency failed to provide any meaningful consideration of whether its regulatory goals could be adequately furthered by alternative measures proposed by Plaintiffs and others in their comments to the Proposed Rule, all of which would have imposed less severe burdens on the constitutional and marketing interests of cigarette manufacturers.

F. THE RULE WILL VISIT CONCRETE AND PARTICULARIZED HARM ON PLAINTIFFS

65. The Rule will directly cause at least three forms of concrete injury to Plaintiffs.

66. First, to comply with the Rule on its effective date of September 22, 2012, Plaintiffs will need to undertake costly and extensive compliance efforts that necessarily must begin well before the effective date. For example:

a. Plaintiff RJRT has 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

g. In addition to the monetary costs described above, the foregoing tasks will occupy over 4,000 hours of RJRT employee time.

67. Plaintiff Lorillard Tobacco Company ("Lorillard") would be forced to incur similar costs, including:

a. Lorillard will need to modify approximately 207 distinct product packagings.

b. Approximately 823 plates and cylinders must be manufactured in order for Lorillard to create the 207 different product-packaging materials that it must modify. The process will take an estimated 18 to 22 weeks, assuming there are no problems in securing the return of the cylinders to be recycled, no delays occasioned in securing substitute steel bases, and no delays occasioned by the fact that all major cigarette manufacturers may be simultaneously placing very large orders for the engraving of plates and cylinders.

c. Lorillard estimates that the cost of acquiring the new printing plates and cylinders to produce compliant packaging will be no less than $2,250,000.

d. In addition to product packaging, Lorillard would need to modify point-of-sale displays. Approximately 146,000 retail locations have Lorillard point-of-sale materials. Lorillard estimates the cost of modifying its point-of-sale displays to be at least $800,000, which will have to be incurred between now and September 2012.

e. In total, it will cost Lorillard more than $3 million to comply with the Rule.

68. Plaintiffs Commonwealth, Liggett Group, and SFNTC each must also bear substantial costs.

69. Plaintiff Commonwealth has already begun the process of complying with the Rule by, among other things, hiring an outside design agency to redesign over 450 distinct package designs at a cost of approximately $1.4 million. The total cost to Commonwealth of complying with the Rule will be over $2.5 million.

70. Plaintiff Liggett Group has already begun the process of complying with the Rule by, among other things, purchasing new cylinder bases at a cost of over $800,000 and hiring an outside design agency at a cost (thus far) of approximately $400,000. In total, complying with the Rule will cost Liggett Group approximately $4 million. In addition, Liggett Group has so far spent nearly 4,000 person-hours on tasks relating to the transition to new warnings, and estimates

that it will spend many thousands of additional person-hours on such tasks between now and the end of 2012.

71. Plaintiff SFNTC has already begun the process of complying with the Rule by, among other things, hiring an outside design agency to redesign its 30 distinct package designs. In total, complying with the Rule will cost SFNTC over $400,000.

72. Second, in addition to the costs of compliance, Plaintiffs will be severely injured by the placement of the Rule's required warnings on their packaging and advertising, since the Rule violates their rights under the First Amendment to the United States Constitution and the APA.

73. Third, the Rule undermines Plaintiffs' ability to compete with other cigarette manufacturers. The cigarette industry is highly competitive. Because overall use is declining, Plaintiffs compete heavily against one another, as well as against other manufacturers, for market share. And advertising through (1) packaging and (2) print advertisements in direct mail, at retail points of sale, and in magazines, is one of the primary means by which Plaintiffs engage in such inter-brand competition. By severely undermining Plaintiffs' ability to communicate their truthful messages to adult tobacco consumers on their packaging and in their advertising, the Act undermines Plaintiffs' ability to convince adult consumers currently choosing their competitors' brands to switch.

74. Plaintiffs fear that if they do not conform their behavior to the requirements of the Rule, FDA will seize their products. FDA has not disavowed an intention to enforce the new Rule.

75. Plaintiffs' allegations in this Complaint are justiciable.

FIRST COUNT

Judgment That The Rule Violates The First Amendment

76. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-75 of this Complaint, as though fully set forth herein.

77. The Rule violates the First Amendment as applied to Plaintiffs.

78. The warnings imposed by the Rule are not "purely factual and uncontroversial" commercial disclosures aimed at "preventing deception of consumers," *Zauderer*, 471 U.S. at 651, and are therefore subject to strict scrutiny.

79. The warnings do not further any compelling governmental purpose. Indeed, as found by FDA itself, the warnings are unlikely to have any material impact on consumer understanding of smoking risks, consumer intentions regarding smoking, or actual consumer smoking decisions.

80. The warnings are not the least restrictive means available to accomplish any governmental purpose, as numerous alternatives would be no less effective than the warnings but impose lower burdens on Plaintiffs' speech.

81. Even were the Rule subject to the lesser scrutiny applied to purely factual and uncontroversial commercial disclosures, the Rule is nonetheless "unjustified and unduly burdensome." *Zauderer*, 471 U.S. at 651.

82. The warnings imposed by the Rule are unjustified because they would have few if any benefits.

83. The warnings are also unduly burdensome because, despite having few if any benefits, they would compel Plaintiffs to disseminate against their will emotionally-charged graphic anti-smoking messages that would displace large portions of Plaintiffs' packaging and advertising, drown out Plaintiffs' own legitimate attempts to communicate with adult consumers, and undermine Plaintiffs' ability to compete for adult consumers.

84. The Rule also violates the First Amendment as applied to Plaintiffs because, in addition to compelling Plaintiffs to convey the Government's message, the Rule impermissibly burdens Plaintiffs' own speech under *Central Hudson*.

85. The warnings imposed by the Rule do not "directly and materially advance" any substantial governmental interest, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995); rather, as discussed, they will have little if any impact on consumer understanding of smoking risks, consumer intentions regarding smoking, or actual consumer smoking decisions.

86. The warnings likewise burden Plaintiffs' speech "more extensive[ly] than necessary" to serve the purported interests justifying the warnings, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002).

87. Plaintiffs have no adequate remedy at law.

88. Plaintiffs therefore seek the entry of a judgment declaring the Rule unconstitutional as applied to Plaintiffs and an injunction preventing Defendants from enforcing the Rule against Plaintiffs.

SECOND COUNT

Judgment That The Rule Violates 5 U.S.C. § 706(2)(A)

89. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-88 of this Complaint as though fully set forth herein.

90. In promulgating the Rule, FDA acted arbitrarily and capriciously by attempting to justify the Rule (and its rejection of alternatives to the Rule) on grounds that were illogical, contradictory, and without support in the regulatory record, and by employing different standards of analysis to comments supporting the Rule than to comments opposing the Rule.

91. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(A), enjoining FDA from enforcing it, and remanding to FDA.

THIRD COUNT

Judgment That The Rule Violates 5 U.S.C. § 553(b)(3)

92. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-91 of this Complaint as though fully set forth herein.

93. In promulgating the Rule, FDA failed to provide Plaintiffs with meaningful notice as required under 5 U.S.C. § 553(b)(3), by failing to disclose key technical data, methodologies, and assumptions underlying the Rule.

94. Plaintiffs therefore seek an order setting aside the Rule under 5 U.S.C. § 706(2)(D), enjoining FDA from enforcing it, and remanding to FDA.

FOURTH COUNT

Judgment That The Effective Dates In The Act Do Not Come Into Effect Until FDA Issues A Legally Valid Rule

95. Plaintiffs incorporate and reallege each and every allegation contained in paragraphs 1-94 of this Complaint as though fully set forth herein.

96. As explained *supra*, ¶ 35, the Act provides for a single effective date for the new textual and graphic warnings and Related Requirements, which shall be "15 months after the issuance of the regulations required by" Section 201(a) of the Act. 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")); *see also* Act § 103(q)(5), 21 U.S.C. § 387c, note (using identical text to set the effective date for the Related Requirements of FDCA § 902(a)(2)(A)-(C)); Act § 301, 21 U.S.C. § 387t (using identical text to set the effective date for the Related Requirement of FDCA § 920(a)).

97. 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 overhauls of their packaging and advertising. In light of this intent, the Act must be read to tie the effective dates of all cigarette packaging and advertising changes to the "issuance" of regulations by FDA that are constitutionally and procedurally valid. Any contrary reading would frustrate the congressional intent reflected in the Act and create the anomaly that an invalid Rule would have substantial and detrimental legal effect.

98. Plaintiffs accordingly seek a declaration that the new textual and graphic warnings for cigarette packaging and advertising required in section 201(a) of the Act, and the

Related Requirements of the Act, shall become effective as to Plaintiffs 15 months after the issuance by FDA of regulations (as required by section 201(a) of the Act) that are permissible under the United States Constitution and federal law.

99. Plaintiffs seek preliminary and permanent injunctions enjoining Defendants from enforcing against Plaintiffs in this case the new textual and graphic warnings for cigarette packaging and advertising required in section 201(a) of the Act, and from enforcing the Related Requirements of the Act, until 15 months after the issuance by FDA of regulations (as required by section 201(a) of the Act) that are permissible under the United States Constitution and federal law.

PRAYER FOR RELIEF

An actual controversy has arisen between the parties entitling Plaintiffs to a declaration and injunctive relief.

WHEREFORE, Plaintiffs pray that this Court:

(A) enter a judgment declaring the Rule to be an unconstitutional abridgement of the First Amendment to the United States Constitution as applied to Plaintiffs and setting aside the Rule;

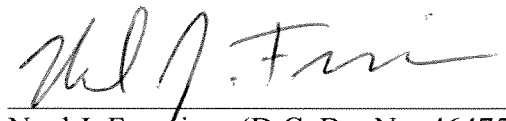
(B) enter a judgment declaring that the Rule violates the APA and setting aside the Rule;

(C) enter a judgment declaring that the new textual and graphic warnings for cigarette packaging and advertising and the Related Requirements required by the Act shall become effective as to Plaintiffs in this case 15 months after the issuance by FDA of regulations (as required by section 201(a) of the Act) that are permissible under the United States Constitution and federal law and that are promulgated in compliance with federal law;

(D) enter a preliminary and permanent injunction enjoining Defendants from enforcing against Plaintiffs in this case the new textual and graphic warnings for cigarette packaging and advertising required by the Rule and section 201(a) of the Act, as well as the Related Requirements of the Act, until 15 months after the issuance by FDA of regulations (as required by section 201(a) of the Act) that are permissible under the United States Constitution and federal law and that are promulgated in compliance with federal law; and

(E) grant Plaintiffs such additional or different relief as it deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

Respectfully Submitted,



Dated: August 16, 2011

Noel J. Francisco (D.C. Bar No. 464752)
Geoffrey K. Beach (D.C. Bar No. 439763)
Warren Postman (D.C. Bar No. 995083)

JONES DAY
51 Louisiana Avenue, NW
Washington, D.C. 20001-2113
Telephone:(202) 879-3939
Facsimile: (202) 626-1700
njfrancisco@jonesday.com
gkbeach@jonesday.com
wpostman@jonesday.com

Floyd Abrams (*pro hac vice* application pending)
Joel Kurtzberg (*pro hac vice* application pending)
Kayvan Sadeghi (*pro hac vice* application pending)

CAHILL GORDON & REINDEL LLP
80 Pine Street
New York, NY 10005-1702
Telephone: (212) 701-3000
Facsimile: (212) 269-5420
fabrams@cahill.com
jkurtzberg@cahill.com
ksadeghi@cahill.com

-and-

Counsel for Plaintiffs R.J. Reynolds and Santa Fe Natural Tobacco Company

Philip J. Perry (D.C. Bar No. 434278)

LATHAM & WATKINS LLP
555 11th Street, NW, Suite 1000
Washington DC 20004-1304
Telephone:(202) 637-2200
Facsimile: (202) 637-2201
phil.perry@lw.com

Counsel for Plaintiff Commonwealth Brands, Inc.

Jonathan D. Hacker (D.C. Bar No. 456553)

O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006-4061
Telephone: (202) 383-5300
Facsimile: (202) 383-5414
jhacker@omm.com

Counsel for Plaintiff Liggett Group LLC

Patricia A. Barald (D.C. Bar No. 218016)
Scott D. Danzis (D.C. Bar No. 481426)

COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
Telephone: 202.662.6000
Facsimile: 202.662.6291
pbarald@cov.com
sdanzis@cov.com

Counsel for Plaintiff Lorillard Tobacco Company