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 SUMMARY JUDGMENT AND PERMANENT 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 to prominently display nine new textual warnings along with disturbing and emotionally-charged graphic images. The new warnings must occupy the top half of both sides of cigarette packaging and the top fifth of cigarette advertising. *See* Act § 201(a), 123 Stat. at 1843; 76 Fed. Reg. at 36,754.

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).

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 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)).

Pursuant to Federal Rule of Civil Procedure 56 and this Court's Local Rule 7, Plaintiffs respectfully move this Court for entry of an Order granting summary judgment on their claim that the new warnings required by the Rule violate the First Amendment, were promulgated without adequate notice in violation of 5 U.S.C. § 553(b)(3), and are arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A).

In support of this Motion, Plaintiffs are filing a Memorandum of Points and Authorities and a Proposed Order. Plaintiffs request oral argument on this Motion.

For the reasons provided in the supporting Memorandum, Plaintiffs contend that there is no genuinely disputed issue as to any material fact and that they are entitled to judgment as a matter of law that the Rule promulgated at 76 Fed. Reg. 36,628 is unconstitutional and was promulgated in violation of 5 U.S.C. §§ 553(b)(3), 706(2)(A). Consequently, Plaintiffs respectfully pray that this Court grant summary judgment in their favor and grant the following relief:

1. A declaration invalidating and setting aside the Rule;
2. An injunction barring Defendants from enforcing the new textual and graphic warnings required by section 201(a) of the Act against Plaintiffs in this case until 15 months after the issuance by FDA of regulations (as required by section 201(a) of the Act) that are substantively and procedurally valid and permissible under the United States Constitution and federal law;
3. An injunction barring Defendants from enforcing the Related Requirements against Plaintiffs in this case until 15 months after the issuance by FDA of regulations implementing section 201(a) of the Act that are substantively and procedurally valid and permissible under the United States Constitution and federal law; and
4. A declaration that Plaintiffs in this case are permitted to continue using their current packaging and advertising until 15 months after the issuance of a new regulation by FDA of regulations implementing section 201(a) of the Act that are substantively and procedurally valid and permissible under the United States Constitution and federal law

Respectfully Submitted,

Dated: August 19, 2011

/s/ Noel J. Francisco

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MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PERMANENT INJUNCTION

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INTRODUCTION

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 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 "Act"), which go far beyond the prior warnings. *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) ("the Rule"). 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, these images must be displayed along with the text 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, these warnings must be printed in color, whereas Plaintiffs' own advertisements would largely be limited to black and white text. Finally, through inclusion of a smoking cessation hotline, every warning must contain a direct exhortation to smokers to "QUIT-NOW." These factors in combination—the use of shocking and manipulative graphics, the size of the graphics and text, their placement on Plaintiffs' packaging and advertising, the directive "QUIT-NOW," and the juxtaposition of color graphics against black-and-white text—make clear that the warnings regime imposed by the Rule does not simply provide factual information to help consumers make educated decisions about cigarette use. Instead, the "warnings" cross the line into anti-smoking advocacy, intended to drown out Plaintiffs' own speech with the Government's message: "Don't Buy This Product."

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 campaign. 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 candidly 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]

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 [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."

[1] FDA, *Tobacco Strategy 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.

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 here. 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. Finally, the Rule also violates the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*

For each of these reasons, Plaintiffs are entitled to judgment as a matter of law.

FACTUAL BACKGROUND

For decades, government-mandated warnings have appeared on all cigarette packages and advertising. *See* 15 U.S.C. § 1333 (2008). These warnings have been part of a "comprehensive Federal program to deal with cigarette labeling and advertising," the express purpose of which was to ensure that the public is "adequately informed about any adverse health effects of cigarette smoking." *Id.* § 1331. The Tobacco Control Act of 2009 imposed yet further restrictions. *See* 21 U.S.C. § 387a-1; 21 C.F.R. § 897.30(b) (1996); 21 C.F.R. §§ 1140.32(a); § 1140.34. As a result, even prior to the Rule, Plaintiffs' remaining avenues of communication with adult consumers were limited principally to: (1) cigarette packaging and (2) print advertising through direct mail, at retail points of sale, and in magazines.[3] In implementing the new textual and graphic warnings required by § 201(a) of the Act, the Rule severely burdens these avenues by commandeering Plaintiffs' packaging and advertising to disseminate graphic anti-smoking messages. 76 Fed. Reg. at 36,753. FDA's own analysis, however, provides no basis to conclude that the warnings will have any impact on smoking, and shows instead that they were chosen for their emotional impact on consumers.

[3] *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 D, Declaration of Robert H. Dunham ("Dunham Decl.") ¶¶ 9-16; *id.*, Affidavit of Victor D. Lindsley III ("2009 Lindsley Decl.") ¶¶ 12-41.

A. The Rule Requires Plaintiffs To Disseminate Shocking And Disturbing Anti-Smoking Graphics On All Packaging And Advertising.

On June 22, 2011, after a period of notice and comment during which FDA received extensive comments on the agency's proposed warnings,[4] FDA issued its final Rule, setting forth the new graphic warnings. FDA made clear that the governmental interest allegedly supporting the Rule is to decrease the rate of smoking among adults and children in the United States, explaining that the warnings "will have a significant, positive impact on public health," 76 Fed. Reg. at 36,631, because they are intended to increase the likelihood that "smokers will reduce their smoking, make an attempt to quit, or quit altogether," *id.* at 36,634.

The warnings required by the Rule must include the following nine textual messages:

- 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.

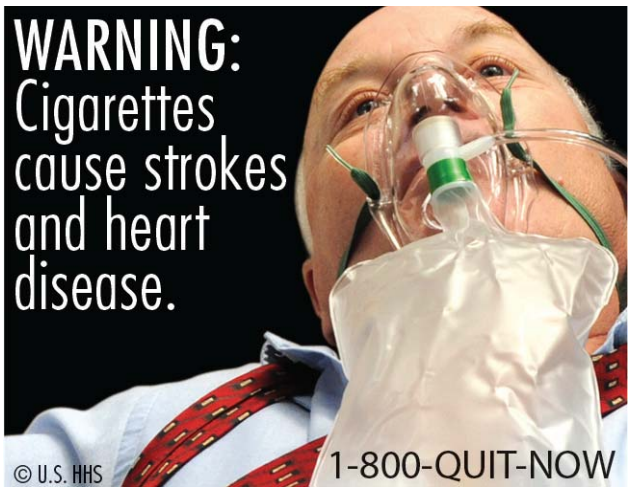
Pub. L. No. 111-31, § 201, 123 Stat. at 1842-43 (amending 15 U.S.C. § 1333(a)).

The Rule also requires, however, that the warning include nine graphic images and occupy the top 50% of the front and back of all packages and the top 20% of all advertisements. The graphics include cartoon images, photographs that use actors and technological manipulation to maximize an emotional response from viewers, and in one instance, an individual wearing a t-shirt depicting the universal "no smoking" symbol and the declaration, "I QUIT." Each warning also includes the "1-800-QUIT-NOW" hotline, thus requiring that Plaintiffs literally urge adult consumers

[4] *See, e.g.*, Comment Letter.

of their lawful products to "QUIT-NOW." Moreover, the graphic warnings must be printed in color, *see* 76 Fed. Reg. at 36,753, whereas Plaintiffs' own advertisements would largely be limited under the Act to black and white text, *see* 21 U.S.C. § 387a-1(a)(2).[5]

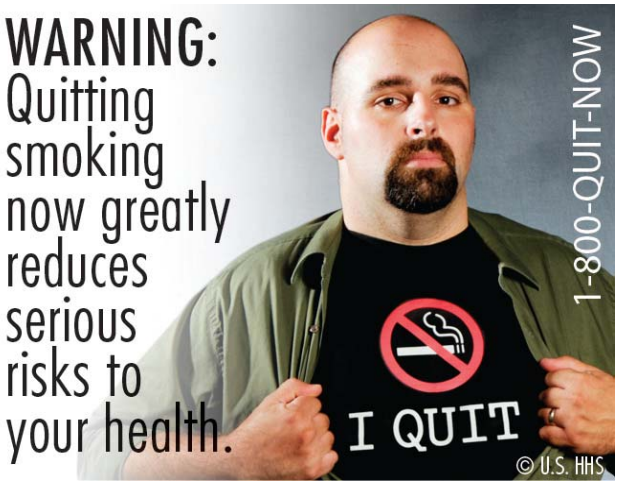
[5] The black-and-white-text requirement has been invalidated by a decision of the United States District Court for the Western District of Kentucky, which is currently on appeal to the United States Court of Appeal for the Sixth Circuit. *See infra* at 16.


WARNING:
Cigarettes cause strokes and heart disease.
© U.S. HHS
1-800-QUIT-NOW


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


WARNING:
Quitting smoking now greatly reduces serious risks to your health.
1-800-QUIT-NOW
I QUIT
© U.S. HHS

B. FDA's Own Analysis Shows That The New Warnings Were Selected For Their Emotional Impact Rather Than Their Ability To Convey Information And Will Have No Material Impact On Smoking Beliefs Or Behavior.

The Rule includes a regulatory impact analysis ("RIA") analyzing the benefits and costs of the new graphic warnings. Although the Rule estimates that the warnings will lead to public health benefits by reducing smoking rates by 0.088%, the RIA *concedes* that this effectiveness estimate is "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. This finding, moreover, is confirmed by a separate study FDA commissioned to analyze the new warnings—which concludes that virtually none of the warnings will have a statistically significant effect on consumers' awareness of smoking risks or smoking intentions—as well as by the views of other experts in the record. With no cited evidence that any graphic warnings would improve consumer understanding or alter smoking intentions, FDA instead chose the final warnings based primarily on their ability to elicit strong emotional reactions from viewers.

1. FDA's RIA Concludes The Estimated Impact Of The Rule On Smoking Rates Is Not Statistically Different From Zero.

The starting point of the RIA's benefits analysis is a comparison of U.S. to Canadian smoking rates. 76 Fed. Reg. at 36,721. In 2000, Canada enacted a graphic warnings requirement similar to the Rule. *Id* . FDA therefore constructed a statistical model describing the trend in smoking rates in the United States and Canada from 1991 to 2000. *Id.* at 36,755. FDA adjusted this model to compensate for the effect of differential cigarette tax rates on smoking prevalence and compared the predictions of the model to actual smoking data in each country from 1991 to 2009. *Id.* For each year, FDA measured any "unexplained difference"—*i.e.*, the difference between actual smoking rates and the smoking rates predicted by FDA's model. *Id.* at 36,755-56. It then assumed that 100% of any unexplained decrease in Canadian smoking rates after 2000 and beyond changes observed in U.S. smoking rates, was caused by the graphic warnings. *Id.* at 36,756. As FDA acknowledged, it "d[id] not account for potential confounding variables." *Id.* at 36,720. That is,

except for the differential in U.S. and Canadian cigarette tax rates, FDA assumed that *any* change in the smoking trend in Canada after 2000, beyond the changes experienced by the United States, was attributable to the introduction of graphic warnings.

The Regulation ultimately estimates that the new warnings may cause smoking rates in the United States to decrease by 0.088%, which would in turn lead to various public health benefits. *Id.* at 36,721. FDA's Uncertainty Analysis, however, concedes:

> [O]ur effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule would not change the U.S. smoking rate.

Id. In other words, FDA cannot reliably conclude that the graphic warnings will reduce the U.S. smoking rate by even one tenth of one percent. *See also* Comment Letter, Exhibit B, Statement of Robert S. Maness ("Maness Report") at 10-1 ("FDA's estimate of [the reduction in smoking rates] is, statistically speaking, not different from an estimate that the graphic warnings would have no effect on smoking rates."). In other contexts, FDA would reject this result altogether. *See, e.g.*, FDA, Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cancer, 58 Fed. Reg. 2,537, 2,541 (Jan. 6, 1993) (rejecting comments relying on "studies with statistically insignificant but generally favorable results" because "[l]ack of statistical significance indicates that such findings could have arisen by chance and thus cannot be used to support a causal relationship"). Dr. Kip Viscusi and Dr. Robert Maness both made the same point in the comments submitted to FDA prior to the issuance of the Rule: there is in fact no evidence that the introduction of graphic warnings in Canada had any statistically significant impact on the trend in Canadian smoking rates.[6]

Moreover, as explained by Drs. Viscusi and Maness, FDA's benefits analysis actually *overestimates* any potential reduction in smoking rates; thus, even FDA's paltry and statistically

[6] *See* Comment Letter, Exhibit A, Statement of W. Kip Viscusi ("Viscusi Report") at 80 ("In the case of Canada, . . . there is no apparent impact at all on the trend in smoking prevalence."); Maness Report at 7 ("[A]s [FDA's] data make clear, this roughly linear downward trend continued [unchanged] post-2000 (*i.e.*, when the graphic warnings were introduced in Canada).").

insignificant reduction (less than one-tenth of one percent) reflects an overly optimistic estimate. There are numerous "confounding factors," other than the presence or absence of graphic warnings and cigarette taxes, that explain the differences between Canadian and U.S. smoking rates after 2000. Maness Report at 12-21. Again, FDA concedes as much, acknowledging that "the U.S. social and policy climate may have been so different from Canada's during the years 1994-2009 that this proxy is inappropriate." 76 Fed. Reg. at 36,776; *see also* Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,532 (Nov. 12, 2010) ("the Proposed Rule") ("It is not possible to draw a direct causal connection between the graphic warnings and [a reduction in smoking rates] because other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking also occurred during the same period.").

For example, since 2000, cigarette prices in Canada have increased at nearly twice the rate of prices in the United States, with only a portion of this increase coming from cigarette taxes. Maness Report at 12-15; 76 Fed. Reg. at 36,711. Because price increases have a well-demonstrated impact on smoking prevalence, FDA's failure to adjust for this factor almost certainly inflated its estimate of the Rule's effects.[7] *See* Maness Report at 12-15. Indeed, FDA's own analysis illustrates the significance of this failure. In its analysis of the Proposed Rule, FDA did not compensate at all for price differences between the United States and Canada and concluded that the Proposed Rule would produce a statistically insignificant reduction in U.S. smoking rates of 0.212%. *See* 75 Fed. Reg. at 69,543. In analyzing the Final Rule, FDA adopted the half-measure of adjusting only for *tax* differentials, and this single correction appears to have caused FDA's estimate of the reduction in smoking to drop by more than half—to a statistically insignificant 0.088%.[8]

[7] Unfortunately, FDA has not provided a sufficient description of its data and models to allow Plaintiffs to replicate FDA's analysis and modify it to account for differentials in cigarette prices. *See infra* at 41-42. *But see* Office of Management and Budget, Circular A-4, at http://whitehouse.gov/omb/inforeg/circular a4.pdf (Sept. 17, 2003) (stating that regulatory impact analyses "must be reproducible").

[8] FDA does not explain why it decided to account only for *tax* differences between the U.S. and Canada, when comments on the Proposed Rule asserted that the RIA should account for *price* differences. *See* Comment Letter at 23; Maness Report at 12-15. FDA surely could have obtained the relevant price data and used econometric

Likewise, Canada's population has aged more rapidly than the population of the United States, which also would cause Canada to have lower overall smoking rates, because smoking prevalence is lower in the over-65 population. Maness Report at 18-19. Yet FDA's analysis erroneously attributes any such reduction in smoking rates to the introduction of graphic warnings. And unlike in the United States, since 2002, 12 of Canada's 13 provinces and territories have either outright banned all retail displays of tobacco products or banned such displays in retail establishments open to minors. *Id.* at 18. Again, FDA's analysis counts any reduction in smoking caused by these retail restrictions as attributable to Canada's graphic warnings.[9]

In short, despite basing its cost-benefit analysis on a nominal but scientifically meaningless decrease in smoking rates in Canada, and despite systematically overstating the portion of this decrease attributable to the warnings, FDA was *still* unable to conclude with any certainty that the Rule would actually affect U.S. smoking rates.[10]

(continued…)

techniques to adjust its model for such data, yet it instead chose to credit the graphic warnings with reductions in smoking that were almost certainly caused by non-tax-based increases in cigarette prices.

[9] In fact, FDA's own model appears to confirm that other confounding factors, apart from graphic warnings, are primarily responsible for the "unexplained" decrease in the smoking trend in Canada. As explained above, FDA's analysis assumes that any unexplained differences between its model and the actual data reflect the impact of graphic warnings, and that the Canadian data provide a close proxy for the United States. If these premises are accepted, one would expect the unexplained difference between the two countries to grow larger *after* 2000, when Canada began required graphic warnings. Instead, the unexplained difference between Canada and the United States *before* 2000 was larger than it was *after* the introduction of Canada's graphic warnings, suggesting that factors that predated the graphic warnings were primarily responsible for the decrease in Canadian smoking rates. *See* Appendix A. Similarly, the average unexplained difference in the United States from 2001-2009 was *greater* than the unexplained difference in Canada from 2001-2009. *Id.* Since Canadian cigarette packaging displayed graphic warnings during this period and U.S. packaging did not, FDA's model should have shown a greater unexplained difference in Canada. Indeed, according to FDA's model, it would appear that the graphic warnings actually caused an *increase* in smoking rates in Canada.

[10] The RIA similarly understates the costs of the new warnings. For example, while FDA acknowledged that "it would be useful to include the effect of the rule on illicit cigarette trading in the regulatory impact analysis," it nonetheless failed to do so, citing "data limitations" that left it "unable to quantify this effect." *Id.* at 36,709. Similarly, the RIA recognized that the Rule would lead to lost wages, *i.e.*, "the difference between wages lost from tobacco-related jobs and the value of next-best options"; however, FDA ignored these costs, because it was unsure of the average period of unemployment that workers might experience when the rule is implemented. *Id.* at 36,717. Likewise, the RIA "agree[d] that a transition from tobacco cultivation to the next-best option entails some loss for farmers," but failed, without explanation, to quantify this effect. *Id.* Nowhere did FDA explain why it could not estimate these costs based on the same approach it used to estimate the Rule's benefits: by reference to Canadian data. Instead, FDA's analysis assumes that all of these acknowledged costs are zero.

2. The FDA Study Confirms That The Rule Will Have No Material Impact On Smoking Behavior Or Beliefs.

FDA also commissioned an "experimental study[]" of the warnings (the "FDA Study"), the "purpose [of which] was to . . . measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels," as well as to assess the relative effectiveness of the warnings among various demographics and the population at large. FDA Study at 1-2. "It tested whether exposure to each of the nine graphic warnings would: (1) increase 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) increase current adult and young adult smokers' intention to quit; and (3) decrease youth non-smokers' likelihood to initiate smoking. *See id*. "The study included approximately 18,000 participants [and] was the largest study of consumer responses to graphic cigarette health warnings ever conducted."[11] The study exposed one group of participants to the text of the new warnings in the format of the current Surgeon General's warnings (side of the package) and another group to the graphic warnings in the Proposed Rule. The study confirms that the larger, graphic warnings will have no impact on smoking behavior or beliefs when compared to providing the same textual information in the format of the current Surgeon General's warnings.

In particular, as to the nine warnings, the FDA Study concludes:

1. *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 same warnings 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.

[11] FDA, Frequently Asked Questions: Final Rule "Required Warnings for Cigarette Packages and Advertisements" ("FDA FAQ"), a*vailable at* http://www.fda.gov/TobaccoProducts/Labeling/CigaretteWarningLabels/ucm259953.htm.

2. *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.*

3. *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.

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

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

6. *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 reported 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.

7. *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.*

8. *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.*

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

Finally, like the RIA, the FDA Study found the new warnings to be ineffective despite being riddled with methodological flaws that caused it to systematically *overstate* the Rule's benefits. Most significantly, 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. As observed by a well-known researcher and prominent anti-smoking advocate:

> Given the widespread harassment of cigarette smokers and the evidence that smoking is actually dangerous to health, it is not surprising that smokers sometimes lie about their smoking. How better for a smoker to avoid the pestering of a physician or other interviewer than to say (whether believing it or not) that he wants to and has even tried to give up cigarettes? And, if the questioner asks if the attempts to stop have been serious, who would want to confess a half-hearted effort? Yet, answers to questions of 'wanting to stop' and 'trying to stop' have regularly been used uncritically—as if smokers now must be telling the truth.

Id. at 45 (quoting L. Kozlowski, *What Researchers Make of What Cigarette Smokers Say: Filtering Smokers' Hot Air*, Lancet, at 699 (Mar. 1980)).[12] "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.[13]

Moreover, the FDA Study drew similar conclusions as to all 36 proposed graphics contained in the Proposed Rule. *See* Viscusi Report at 50, 70-73. This general failure of the 36 proposed warnings casts doubt on even the occasional finding that a particular warning had a particular impact on a particular group. "Repeated testing complicates the interpretation of significance levels. If enough comparisons are made, random error almost guarantees that some will yield 'significant' findings, even when there is no real effect." Federal Judicial Center, Reference Manual on Scientific Evidence 127 (2d ed. 2000).[14] The FDA Study assessed the impact of 36 warnings across 3 criteria (smoking risk awareness, ETS risk awareness, and smoking intentions) for 3 groups (youth, young

[12] *See also* G. Giovino et al., *Trends in Cigarette Smoking Cessation in the United States*, 2 Tob. Control S3, S9 (1993) ("In 1991, 76% of current smokers stated that they wanted to quit, and the number hasn't changed much over time. Answering 'no' to this question is probably a socially unacceptable answer. We will need to consider that in our deliberations."); S. Chapman, *Smokers: Why Do They Start -- And Continue?* 16 World H. Forum 1, 7 (1995) ("Plainly, social contexts in which smoking is increasingly vilified can produce a gap between what people feel obliged to say to researchers and what they genuinely feel.").

[13] Indeed, FDA itself relies on studies elsewhere in the Rule that show stated smoking intentions to be an extremely poor predictor of actual smoking decisions. *See* 76 Fed. Reg. 36,633 (citing studies finding that a far higher percentage of survey participants predict that they will quit than actually do so for the proposition that consumers "lack adequate understanding of the addictive nature of cigarettes").

[14] *Available at* http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/$file/sciman00.pdf.

adults, and adults), thereby providing the graphic warnings 324 opportunities to demonstrate a significant impact on at least one criterion for one group. The fact that only a handful of graphic warnings led to significant results on isolated criteria is therefore of little meaning. "Ten heads in the first ten tosses means one thing; a run of ten heads somewhere along the way in a few thousand tosses of a coin means quite another." *Id.*

Notwithstanding these and other flaws, the FDA Study, like the RIA, *still* concludes that the benefits of the graphic warnings ranged from negligible to non-existent.

3. Independent Studies In The Administrative Record Confirm FDA's Conclusions In The RIA and FDA Study.

FDA's findings in the RIA and the FDA Study are not surprising. They reflect the well-known fact that the health risks of smoking have 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. Viscusi Report at 15. It is, however, well established that telling people what they already know, but in ways designed to grab their attention, is not effective at changing behavior.

Americans, young and old alike, are well aware of the health risks of smoking. More people are aware that smoking causes lung cancer than "are aware that George Washington was the first U.S. President [or] that the Earth revolves around the Sun." *Id.* at 10. This is true for each of the nine specific subjects of the warnings. *Id*. at 16-31. Indeed, the public actually *overestimates* the risks from smoking 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. 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.

It is also well documented that where, as here, the public is well aware of the risks of an

activity, reiterating those risks, even if in a more visible format, does not change behavior. As far back as 1994, 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)
> . . .
> Comprehensive reviews published at that time concluded that smoking-prevention programs based on the information deficit approach were not effective.

Id. More recent studies have confirmed the continuing validity of the Surgeon General's observation. *See id.* at 21-24 (discussing "[i]ndependent studies that have demonstrated that more information about the risks of smoking does not influence smoking rates"). As Dr. Viscusi further details, "[w]hen it comes to the dangers of smoking, consumers' benefit-cost analyses of cigarettes are essentially impervious to more information . . . . [a]dditional or different information that conveys the risks of smoking will therefore not alter consumer behavior." *Id.* at 30-31. Thus, the finding of the RIA and the FDA Study that the Rule would likely have no material impact on smoking behavior or beliefs is consistent with a long line of research.

4. FDA Selected The Warnings For Their Emotional Impact.

In selecting the final 9 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 ("[T]he responses on the salience measures served as a primary basis for distinguishing among the 36 proposed required warnings."). Those salience measures did not measure the impact of the warnings on consumer awareness of smoking risks or quit intentions—as discussed above, the study separately

measured those factors and for the most part found that the warnings had no impact. Instead, "salience" purportedly estimates 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 & n.3 (internal quotation marks omitted). In the words of Commissioner Hamburg and Secretary Sebelius, the warnings were chosen to convert "every single pack of cigarettes in our country . . . [into] a mini-billboard" and thereby "rebrand[] our cigarette packs." *See supra* notes 1-2.

C. Plaintiffs' Separate Facial Challenge To The Tobacco Control Act.

Various tobacco product manufacturers, including some of the Plaintiffs in this action, have challenged various speech restrictions mandated by the Act in the United States District Court for the Western District of Kentucky. The District Court invalidated the Act's ban on color and imagery in tobacco advertising and one other provision, but rejected the other challenges to the Act, including the plaintiffs' challenge to the general statutory requirement that cigarette packaging and advertising display graphic warnings. *See Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010). Both sides have appealed the *Commonwealth Brands* decision to the Sixth Circuit. *See Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235. Plaintiffs Liggett Group and Santa Fe Natural Tobacco Company are not parties to that action.

The plaintiffs in *Commonwealth Brands* have argued that the Act's general graphic warnings requirement is facially unconstitutional. The *Commonwealth Brands* plaintiffs did not raise the claim brought by Plaintiffs here—that the particular warnings required by the Rule are unconstitutional—because the Rule had not yet been promulgated when that case was filed. As FDA noted, 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. This action challenges the specific warnings promulgated by the Rule in "its exact form." It turns primarily on facts not available, litigated, or considered in the *Commonwealth Brands* case.

ARGUMENT

I. THE RULE VIOLATES THE FIRST AMENDMENT.

The Rule violates the First Amendment under any standard of review. It compels Plaintiffs to disseminate the Government's graphic anti-smoking message and, therefore, is subject to strict scrutiny, which it cannot possibly satisfy. *See Wooley*, 430 U.S. at 714; *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995). Even if erroneously treated under the standard applicable to "purely factual and uncontroversial" informational disclosures, the Rule is still unconstitutional because it is "unjustified [and] unduly burdensome." *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). Finally, the Rule unconstitutionally burdens Plaintiffs' right to engage in commercial speech. *See Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980).

A. The Rule Is Subject To And Unconstitutional Under Strict Scrutiny.

The First Amendment protects "both the right to speak freely and the right to refrain from speaking at all." *Wooley*, 430 U.S. at 714. This flows from "the fundamental rule of protection under the First Amendment, that a speaker has the autonomy to choose the content of his own message." *Hurley*, 515 U.S. at 573-74. Nor is this "fundamental rule" limited to individuals. "For corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion). As explained in *Hurley*:

> Since *all* speech inherently involves choices of what to say and what to leave unsaid, one important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say. Although the State may at times prescribe what shall be orthodox in commercial advertising by requiring the dissemination of purely factual and uncontroversial information, outside that context it may not compel affirmance of a belief with which the speaker disagrees. . . . Nor is the rule's benefit restricted to the press, being enjoyed by business corporations generally and by ordinary people engaged in unsophisticated expression as well as by professional publishers. Its point is simply the point of all speech protection, which is to shield just those choices of content that in someone's eyes are misguided, or even hurtful.

515 U.S. at 573-74 (internal citations and quotation marks omitted). Thus, unless a law compelling speech requires only "the dissemination of purely factual and uncontroversial information," *id.*, it is subject to the same strict scrutiny governing other content-based speech rules, *United States v. Playboy Entm't Grp.*, 529 U.S. 803, 813 (2000).

For example, in *Wooley*, the Supreme Court invalidated a New Hampshire statute that forced drivers to display on their license plates the state motto "Live Free or Die," thereby "effect[ively] requir[ing] [them to] use their personal property as a 'mobile billboard' for the State's ideological message." 430 U.S. at 715. Likewise, in *Entertainment Software Association v. Blagojevich*, the Seventh Circuit invalidated a state law requiring video-game sellers to display a four-square-inch sticker stating "18" on games that fell within the law's definition of "sexually explicit." 469 F.3d 641, 651-52 (7th Cir. 2006). The court reasoned that "[t]he sticker ultimately communicate[d] a subjective and highly controversial message—that the game's content [was] sexually explicit." *Id.* It then invalidated the law, holding that "at four square inches, the '18' sticker *literally* fails to be narrowly tailored." *Id.* The court likened this to an overly-large health warning, reasoning: "Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning." *Id.* The court also noted that the State could have pursued its goal through less intrusive means, such as "a broader educational campaign." *Id.* As the Court recently held in *Sorrell*, "[t]he State can express [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." 2011 WL 2472796, at *17.

The application of strict scrutiny in this context reflects the First Amendment's intolerance of laws that target speech according to its viewpoint. Like other forms of viewpoint discrimination, a requirement that a speaker promote a particular point of view in lieu of his or her own is "censorship in a most odious form." *Police Dept. of Chi. v. Mosley*, 408 U.S. 92, 98 (1972) (quoting *Cox v.*

Louisiana, 379 U.S. 536, 581 (1965) (Black, J., concurring); *see also Blagojevich*, 469 F.3d at 651 ("The Court has stated that where a statute 'mandates speech that a speaker would not otherwise make,' that statute 'necessarily alters the content of the speech.'" (quoting *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988))). As such, compelled speech is, like other forms of viewpoint discrimination, "presumptively unconstitutional." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 830 (1995).

Here, the warnings plainly convey the Government's viewpoint that the risks associated with smoking cigarettes outweigh all other considerations and, therefore, that no one should use these lawful products. Indeed, through the inclusion of the smoking cessation hotline, Plaintiffs are literally required to exhort their consumers to "QUIT-NOW." This is hardly content-neutral speech. The Rule therefore falls outside the exception to strict scrutiny for purely factual and uncontroversial disclosure requirements. As a result, it is subject to strict scrutiny, which FDA does not even contend that it could survive.

1. The Rule Is Not Limited To The Disclosure Of "Purely Factual And Uncontroversial Information."

The Government argues that the Rule is not subject to strict scrutiny because the graphic warnings are purely informational disclosures, no different than the existing Surgeon General's warning or the "poison" warning on a toxic chemical. *See* 76 Fed. Reg. at 36,695. Although certain disclosure requirements are subject to a lower standard of scrutiny, *Zauderer*, 471 U.S. at 651,[15] this is a narrow exception to "the fundamental rule . . . that a speaker has the autonomy to choose the content of his own message," *Hurley*, 515 U.S. at 573-74. As the D.C. Circuit recently cautioned, to fit within this narrow exception, the compelled speech "must [be] confine[d] . . . to '*purely factual and uncontroversial information.*'" *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1144-45

[15] Plaintiffs believe that strict scrutiny should govern *all* commercial-speech restrictions, including mandated disclosures. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1342-43 (2010) (Thomas, J., concurring in part and concurring in the judgment). Although Plaintiffs expressly preserve that issue for later review, this brief applies controlling precedent.

(D.C. Cir. 2009) (quoting *Zauderer*, 471 U.S. at 651) (emphasis added). Here, Plaintiffs do not challenge the dissemination of the purely factual information contained in the text of the new warnings. Rather, Plaintiffs challenge the graphic warnings as mandated by the Rule. These warnings contain graphics that, by themselves, convey an emotionally-charged anti-smoking message. Moreover, regardless of the impact of these graphics alone, a combination of factors—*e.g.*, the warnings' shocking color graphics, the unnecessary size of the warnings' graphics and text, the warnings' placement on the top of cigarette packs and advertisements, and the juxtaposition of color "warnings" against black-and-white text in Plaintiffs' advertising—make crystal clear that the warnings are not the sort of purely factual and uncontroversial disclosures that fit within *Zauderer*'s narrow exception to strict scrutiny.

First, FDA effectively concedes that the warnings are not intended to inform, but rather, to persuade consumers not to smoke. In the words of Secretary Sebelius, the warnings convey the message that "smoking is gross" and "dispel[] the notion that somehow [tobacco use] is cool." *See* Press Briefing, *supra* note 2. They are, as Secretary Sebelius put it, part of FDA's efforts to "help encourage smokers to quit." *See* FDA News Release, *supra* note 1. According to the Act itself, the warnings are intended to negate the view that smoking is "socially acceptable." 21 U.S.C. § 387 note, Findings (17). FDA, moreover, admits that it used measures of "salience" "as a primary basis for distinguishing among the 36 proposed required warnings." 76 Fed. Reg. at 36,639. As noted above, "salience" is a euphemism for the FDA Study's findings that the graphic warnings 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). FDA claimed that such emotional reactions would, in turn, "motivate positive behavior change." *Id.* at 36,652. Indeed, FDA relied on measures of "salience" despite evidence that "recall of associated warning message statements may be *reduced* in the short term by moderately or highly graphic pictorial warnings

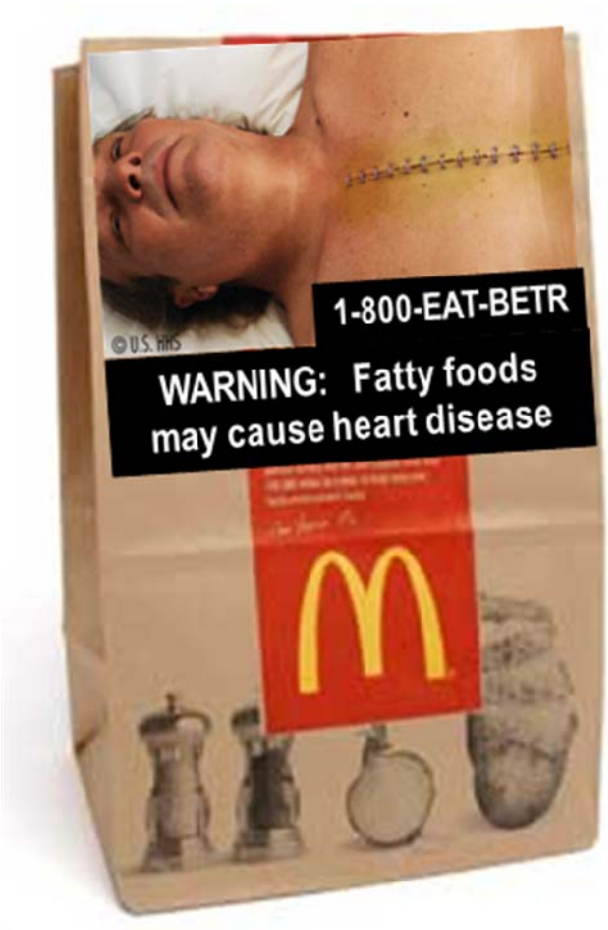
versus text-only controls or less graphic pictorial warnings," reasoning that "these warnings [might] still increase intentions to quit *through evoked emotional responses*." *Id.* at 36,639 (emphases added).[16] Consequently, FDA concedes that it selected the warnings based not on their efficacy in conveying factual information, but rather, their anticipated emotional impact.

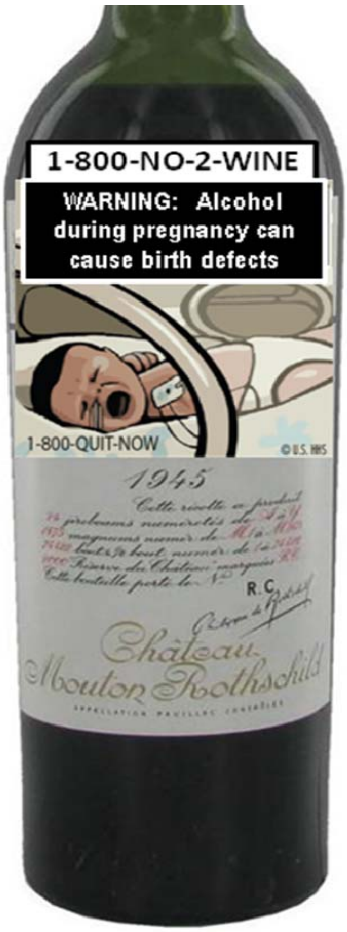
Second, and relatedly, the objective message conveyed by the new warnings is not "purely factual and uncontroversial." These images include non-factual cartoon drawings and digital enhancements to dramatize and exaggerate the effects of sickness and disease. One goes so far as to place a gratuitous autopsy scar on an actor portraying a cadaver, as if autopsies were a common result of cigarette smoking. Others display a mouth with discolored teeth and cancerous lesions, a cartoon drawing of a baby in an incubator, a woman crying, a technologically enhanced man smoking through a tracheotomy hole (it is unclear whether this is an actual photograph or a digitally created one), and a man (apparently another actor) proudly wearing a t-shirt depicting the universal "no smoking" symbol and declaring "I Quit." *None* of the nine graphic images required by the Rule provides "purely factual and uncontroversial" information about the health risks of tobacco products. *Zauderer*, 471 U.S. at 651. Rather, they are self-evidently designed to evoke an emotional response in service of the Government's viewpoint about how people should act in response to the well-known health risks associated with smoking. As was recently reported on a popular news program, "The whole idea is that the labels will grab people by the lapels and be the visual equivalent of someone yelling: 'Stop smoking!'"[17]

[16] *See also id.* at 36,641 ("[T]he responses on the salience measures served as a more important basis than recall [of the textual warnings] for distinguishing among the 36 proposed required warnings."); *id.* at 36,635 ("We have chosen a balanced set of images, including those that may arouse fear and those that may generate other emotional responses in certain individuals in order to reach a diverse population of smokers and nonsmokers, as well as youth, young adults, and adults."). As already explained, *supra* at 7-15, even this rationale for the warnings is contradicted by the evidence in the record, including the Canadian experience with graphic warnings, which FDA concedes never had any statistically significant effect on decreased prevalence and FDA's own estimates that the warnings required by the Rule will not have a statistically significant impact on U.S. smoking rates.

[17] Scott Hensley, *Be Warned: FDA Unveils Graphic Cigarette Labels*, NPR.org (June 21, 2011), *available at* http://www.npr.org/blogs/health/2011/06/21/137316580/be-warned-fda-unveils-graphic-cigarette-labels?ps=sh_stcatimg.

Such tactics are no closer to mere informational disclosures than any of the "shock and awe" advocacy used in numerous ideological debates, such as when animal-rights activists display photographs of mutilated animals. Although such photographs illustrate the actual treatment of animals, no one would contend that they are "*purely* factual and uncontroversial." *Id.* (emphasis added). To the contrary, such images are, by design, intended to "shock" others into agreeing with the non-factual and controversial message that the targeted practice is socially unacceptable and should be stopped. Similarly, no one would contend that the Government could mandate the following as "purely factual and uncontroversial" warnings:





To contend otherwise based on the (erroneous) assertion that the images depict situations that are, in a technical sense, "factual," requires ignoring all context. The Rule's graphic warnings are no more "purely factual and uncontroversial" than the above images.

Third, the Rule requires the warnings to include "1–800–QUIT–NOW," which is a "reference to a smoking cessation assistance resource." 76 Fed. Reg. at 36,684. Such "disclosure," however, conveys no factual information about the risks of tobacco use. Instead, like the image of the man wearing a t-shirt with the international "no smoking" symbol and the words "I QUIT," it literally forces Plaintiffs to communicate the subjective policy message "QUIT–NOW." That may be a message that the Government wishes to send. But forcing companies that are in the business of *selling* a lawful product to disseminate to their customers the message "QUIT–NOW" is not even arguably "purely factual and uncontroversial."

Fourth, the size of the warnings, as well as the requirements that they be placed on the top of both sides of the package and be printed in color above only black-and-white advertising by Plaintiffs, indicate that the warnings are not intended simply to convey factual information to consumers. Indeed, in 1996, FDA *rejected* comments suggesting that the current Surgeon General's warnings should occupy a larger percentage of cigarette packaging or be augmented with "graphic enhancements to make the information in the brief statement more noticeable" because "the current Surgeon General's warnings [we]re sufficient" as a means of conveying the "'relevant warnings, precautions, side effects, and contraindications'" of cigarettes. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,521 (Aug. 28, 1996) (quoting 21 U.S.C. § 352(r)). Although the agency now conclusorily suggests that the Surgeon General's warnings "fail to convey relevant information in an effective way," 75 Fed. Reg. at 69,525, it provides no reasoned or scientific basis for this change in position. Indeed, the fact that no other addictive or dangerous product subject to regulation by FDA is required to display warnings like those required here reflects FDA's judgment that warnings need not dominate the package or include graphic images in order to effectively communicate risks to the public. Instead, when one considers the size and location of the multiple warnings *plus* the shocking color graphics, *plus* the nonfactual nature of the graphics, *plus* the limitation of Plaintiffs' advertising

to black-and-white text, it is clear that the graphic warnings regime is designed not to inform, but to force Plaintiffs to mute their own speech and instead *shout* the Government's views about how people should lead their lives: that the risks from smoking outweigh the pleasure smokers derive from it; that smokers make bad personal decisions; and, therefore, that they should stop smoking.

Finally, given that the warnings were selected and designed to maximize emotional impact, it is not surprising that FDA's own findings confirm that the graphic warnings will not affect consumer understanding. As explained in detail above, the FDA Study concluded that the graphic warnings will have no material impact on consumer understanding of smoking risks, consumer intentions regarding smoking, or actual consumer smoking decisions. Likewise, FDA's RIA concluded that its effectiveness estimates "are in general not statistically distinguishable from zero." *See supra* at 8. Moreover, FDA reached these findings despite placing a heavy thumb on the scale in favor of finding the warnings to be effective. These conclusions reflect the fact that the American public is already fully aware of the health risks of smoking and the graphic images required by the warnings do not provide new information.

In sum, although the Government may, under *Zauderer*, have a limited right to force commercial actors to disclose "purely factual and uncontroversial" information about their products so that consumers can make rational purchasing decisions, it has no right to force manufacturers to convey an emotionally-charged anti-smoking message. The Government could not force Plaintiffs to print "Don't Smoke" on their packages, and it cannot rely on graphic images and the "1-800-QUIT-NOW" hotline to send the same message. The Government may, of course, disseminate that message itself, but the First Amendment forbids it from forcing tobacco manufacturers to serve as its mouthpiece by conscripting their private property "as a 'mobile billboard' for [its] ideological message," *Wooley*, 430 U.S. at 715.

2. The Rule Clearly Fails Strict Scrutiny.

To pass muster under the strict scrutiny standard, FDA bears the burden of demonstrating that the Regulations are "narrowly tailored to promote a compelling Government interest" and that no "less restrictive alternative would serve the Government's purpose." *Playboy Entm't Grp.*, 529 U.S. at 813. "Only rarely are statutes sustained in the face of [this standard]. . . . [S]trict-scrutiny review is strict in theory but usually fatal in fact." *Bernal v. Fainter*, 467 U.S. 216, 219 n.6 (1984) (internal quotation marks omitted). FDA cannot possibly meet this standard; and, in the final Rule, it did not even try. *See* 76 Fed. Reg. at 36,695.

a. The Rule Will Not Further The Government's Public Health Interest.

The Rule will not further any of the governmental interests it is supposed to serve. As explained above, FDA's own RIA concluded that its estimate of the impact of the warnings on smoking rates is "in general not statistically distinguishable from zero." *See supra* at 8. Likewise, the FDA Study found that the graphic warnings will have no material impact on consumers' understanding of smoking risks, intentions regarding smoking, or actual smoking decisions. *See supra* at 11-14. Nor do the various studies referenced in the Rule, *e.g.*, 76 Fed. Reg. at 36,629, justify a contrary conclusion, because they do not refute either of two critical facts: (1) the introduction of graphic warnings in Canada had no statistically significant impact on Canadian smoking rates, and (2) Americans are fully aware of and, indeed, overestimate the major risks of smoking. Instead, they support three unremarkable and irrelevant propositions.

First, FDA cites many of these studies for the proposition that the existing warnings "have largely gone unnoticed by both smokers and nonsmokers." 76 Fed. Reg. at 36,632. But this simply reflects the fact that consumers have been inundated for decades with the underlying facts regarding smoking and health. *See* Viscusi Report at 23. For example, assume that a person works in an office bearing his or her name outside the door. That person has no reason to "notice" the nameplate after

the first or second day at work because he or she knows what it says. The Government's citations regarding attention to the warnings merely complain, by analogy, that the worker does not look at his or her nameplate each day, while ignoring that there is no need to do so. Consequently, these references in no way support the assertion that there is an information deficit regarding the substantive content of the warnings—to the contrary, they only reinforce that the information contained in the existing warnings is well known.[18]

Second, FDA also relies on studies that concede that consumers generally understand that smoking is addictive and fatal,[19] but find that consumers do not know specific details about particular smoking risks, such as whether smoking causes stomach ulcers or osteoporosis, or reduces average life expectancy by a specified number of years. *See* 76 Fed. Reg. at 36,632. But "[s]mokers need not know about every health risk associated with smoking to be making an informed choice. All that is required is that they are sufficiently aware of the health risks to be deterred from smoking to the same degree as they would if they had full information." Viscusi Report at 23; *see also id* at 17-32 (describing numerous studies showing that because "the public is not only aware of the dangers of smoking, but also substantially overestimates the associated risks[, a]dditional or different information that conveys the risks of smoking will therefore not alter consumer behavior"). More fundamentally, referencing these studies is a *non sequitor*. None of the graphic images that Plaintiffs challenge conveys the information these studies claim consumers lack. The fact that some

[18] Indeed, what FDA does *not* cite is also quite telling. In the FDA Study itself, every study participant was asked, prior to viewing the graphic warnings or a control, whether they believed a regular smoker is likely to suffer from various smoking-related illnesses. FDA Study, App. A at 1. As a result, the FDA Study's raw data would provide the most recent and expansive set of evidence available regarding consumers' knowledge of the risks of smoking. Yet FDA not only failed to cite this data in its Rule; it also failed even to disclose it.

[19] Weinstein N.D., et al., *Public Understanding of the Illnesses Caused by Cigarette Smoking*, Nicotine & 6 Tobacco Research 349–55 (2004) ("When lung cancer, emphysema, and heart disease are mentioned to survey respondents, most respondents now agree that cigarettes can cause those illnesses."); Hammond, D. et al., *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings From the International Tobacco Control (ITC) Four Country Survey*, 15 Tobacco Control iii19–iii25 (2006) ("Most smokers reported that smoking causes lung cancer and heart disease . . . ."); Cummings, K.M., et al., *Are Smokers Adequately Informed about the Health Risks of Smoking and Medicinal Nicotine?*, 6 Nicotine & Tobacco Research Supp. 333–40 (2004) ("[P]opulation surveys show that most people today recognize major health risks from smoking . . . .").

consumers may not know cigarettes cause stomach ulcers or osteoporosis does not justify an image of a dead body with an autopsy scar, diseased lungs and gums, a woman crying, a cartoon of a suffering infant, or any of the other images the Rule requires.

Third, FDA relies on surveys that ask individuals whether graphic warnings are "effective," or make them think more about the health risk of smoking, or make them intend or try to quit smoking. 76 Fed. Reg. at 36,633-34. These studies suffer from the methodological flaw of "social desirability bias," which, as described above, causes such studies "to significantly overestimate the number of smokers who actually intend to quit as a result of the proposed warning." Viscusi at 63; *see supra* at 12-13. More importantly, these types of studies, like the "salience" measures assessed in the FDA Study, are simply surrogate means for testing the actual impact of warnings on smoking rates in the absence of direct evidence. *See* 76 Fed. Reg. at 36,634 (finding that comments critical of the Rule were "not persuasive" because "[w]hile focus groups can provide useful information, it is well known that they are not as reliable as real-world evidence for drawing conclusions about causal relationships and generalizing results to the population as a whole"). Here, however, the direct "real-world" evidence is clear, unambiguous, and undisputed: as FDA itself found, the introduction of graphic warnings in Canada—the country that "culturally and geographically, . . . provides a closer comparison for the United States than any other country," 76 Fed. Reg. at 36,712—has not had any statistically significant impact on Canadian smoking rates. Moreover, even were one to consider surrogate evidence, the most relevant evidence available likewise shows that the graphic warnings will have no impact: that is, the FDA Study—which studied the impact of the precise warnings at issue on consumers in this country, and was the "largest [and most recent] study of consumer responses to graphic cigarette health warnings ever conducted"[20]—found that the graphic warnings had no meaningful impact even on consumers' reported intentions to smoke.

Finally, the Supreme Court's recent opinion in *Brown v. Entertainment Merchant*

[20] FDA FAQ.

Association, __ S. Ct. __, 2011 WL 2518809 (June 27, 2011), underscores that the Government must show that a compelling interest is served by the *incremental benefit* of the proposed statute—here, that the Rule serves a compelling interest by providing a necessary change to the existing warning regime already in place. In *Brown*, the Court rejected the state's assertion that a law governing violent video games furthered a general interest in aiding parental authority, because the proper inquiry was not the broad goal, but rather the incremental benefit provided by the law. *Brown*, 2011 WL 2518809, at *9. Here, FDA has made no showing that the Rule will provide an incremental benefit over the existing warning regime, or a less restrictive regime such as new and smaller textual warnings without graphics. Indeed, if, as the Court held in *Brown*, "the government does not have a compelling interest in each marginal percentage point by which its goals are advanced," *id.*, *a fortiori*, it lacks a "compelling interest" when it cannot reliably conclude that the Rule will reduce smoking rates by a statistically insignificant 0.088%.

b. The Rule Is Not The Least Restrictive Means Of Furthering The Government's Public Health Interest.

The Rule also is not the *least restrictive* means available for communicating FDA's anti-smoking message. To the contrary, a host of alternatives offer plausible avenues for furthering the Government's interest, none of which would infringe on Plaintiffs' free speech rights at all.

Most obviously, the Government could disseminate its anti-smoking message itself. It could, for example, increase funding for anti-smoking advertisements on television and radio and in other media to depict its chosen imagery. It could also issue additional statements in press conferences, press releases, government reports, and public hearings, to urge consumers to quit smoking and avoid cigarettes. The availability of such alternatives is precisely the basis upon which the Supreme Court and lower courts have repeatedly invalidated speech restrictions.[21]

[21] *See, e.g.*, *Wooley*, 430 U.S. at 717 ("[T]he State may legitimately pursue [its] interest[]" in "disseminat[ing] an ideology" "in any number of ways," but not by forcing "an individual[] . . . [to] becom[e] the courier for such message."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (citing educational campaigns by the government as "perfectly obvious . . . alternative forms of regulation that

There are, moreover, numerous other less restrictive alternatives, as explained in detail in the declaration of Dr. Cecil Reynolds and the report of Dr. Viscusi:

- The MSA annually provides the States with billions of dollars intended for tobacco-control programs. The federal Centers for Disease Control and Prevention ("CDC") has found that requiring the States to increase the allocation of MSA funds to youth tobacco prevention—from the meager 3.5% recently employed to the still-modest CDC-recommended 15%—would be effective in reducing tobacco use. *See* Comment Letter, Exhibit D, Declaration of Cecil Reynolds ¶¶ 54-57 ("C. Reynolds Decl."). The Government therefore could use its power under the Spending Clause, U.S. Const. Art. I, § 8, cl. 1, to condition receipt of federal funds on States' allocation of MSA funds in accordance with CDC recommendations. *See South Dakota v. Dole*, 483 U.S. 203, 206-08 (1987).

- There are, moreover, literally dozens of non-speech-restrictive strategies that federal agencies and the public-health community believe would reduce youth tobacco use, because they address the social factors that directly influence such use. *See* C. Reynolds Decl. ¶¶ 28-30, 50-66. As Dr. Reynolds explains, the existing but limited deployment of these strategies has already proven effective in reducing youth tobacco use. *See id.* ¶¶ 6-8, 20, 23.

- The Government likewise could improve efforts to prevent the unlawful sales of tobacco products to minors. Previous federal efforts in this regard have proven to be extraordinarily effective, and could be strengthened. *See* C. Reynolds Decl. ¶¶ 52, 61.

- As it has done with prescription drugs and devices, the Government could provide an exemption from the graphic warnings requirement for "reminder" advertising and labeling, which is a well-established category for several FDA-regulated products. Reminder advertisements, which simply call attention to the name of a product and provide certain other information, but which do not make any express or implied claims about the product, are exempt from the requirement to include product warnings. *See, e.g.*, 21 C.F.R. § 201.100(f) (prescription drug exemption); *id.* § 801.109(d) (prescription medical device exemption).

- The Government could also consider whether increased cigarette taxes, which have been shown to reduce cigarette consumption, would be at least as effective as the Rule. *See* Viscusi Report at 33.

Finally, at a minimum, the Government could modify the health warnings to make them less burdensome. It could, for example, (1) reduce the packaging and advertising space occupied by the

(continued…)

would not involve any restriction on speech"); *Blagojevich*, 469 F.3d at 650 ("[T]he plaintiffs have identified other less restrictive alternatives . . . [m]ost obviously, the State could have simply passed legislation increasing awareness among parents of the voluntary [video game] ratings system.").

proposed warnings to no more than 20 percent of cigarette packaging and 10 percent of cigarette advertisements; (2) require warnings on only the front *or* back of packaging but not both; (3) allow warnings to be placed on the bottom, rather than the top, portion of packaging and advertising; (4) select graphics that convey purely factual information, rather than trying to inspire loathing or disgust for the product; or (5) some combination of the above. Regardless of whether such alternatives would ultimately satisfy the First Amendment, the availability of these alternatives undermines any claim that the Rule is the *least* speech-restrictive means of satisfying any legitimate governmental interest. Indeed, as in *Blagojevich*, the graphic warnings, which occupy the top half of both sides of all packaging and the top fifth of all advertising, "*literally* fails to be narrowly tailored—the [warning] covers a substantial portion of the box. The [Government] has failed to even explain why a smaller [warning] would not suffice." 469 F.3d at 652.

In sum, if the Government wants to disseminate its anti-smoking viewpoint, it must find other ways to do so. It may well be more convenient and less expensive for the Government to conscript cigarette manufacturers' property to disseminate its message. But the Constitution stands as a bulwark against such coercive deployment of governmental power: "Citizens may not be compelled to forgo their constitutional rights because officials . . . desire to save money." *Palmer v. Thompson*, 403 U.S. 217, 226 (1971). And "[t]he State may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 2011 WL 2472796, at *17. Accordingly, because the Rule neither furthers any compelling governmental interest nor employs the least speech-restrictive means in pursuit thereof, the Rule cannot satisfy strict scrutiny and, therefore, violates the First Amendment.

B. In Any Event, Even Under *Zauderer*'s Standard For "Purely Factual And Uncontroversial" Disclosure Requirements, The Rule Is "Unjustified And Unduly Burdensome."

Even if erroneously treated as limited solely to the dissemination of "'purely factual and uncontroversial information,'" *Philip Morris USA Inc.*, 566 F.3d at 1144-45 (quoting *Zauderer*, 471 U.S. at 651), the Rule is still unconstitutional, because it is "unjustified [and] unduly burdensome." *Zauderer*, 471 U.S. at 651. Under *Zauderer*, the Court must weigh the benefits of the Rule against the burdens it imposes on Plaintiffs and other cigarette manufacturers. But in contrast to the enormous burden that the Rule imposes on Plaintiffs, FDA's own analysis, confirmed by the Viscusi and Maness Reports, demonstrates that the Rule will have no material effect on consumer beliefs or behavior. It is therefore difficult to imagine a "disclosure" requirement that more decisively fails the *Zauderer* test.

Indeed, the cases in which the courts have upheld purely factual and uncontroversial informational disclosures imposed straightforward and minimally burdensome factual warnings aimed at preventing consumer confusion or ignorance. For example, in *Zauderer* itself, the Court upheld an attorney-disciplinary rule that merely required contingency-fee advertisements to disclose that contingent-fee clients "would be liable for costs (as opposed to legal fees) even if their claims were unsuccessful." 471 U.S. at 633. This requirement was not "unjustified or unduly burdensome," the Court reasoned, because an attorney's interest in not providing this factual information was "minimal," *id.* at 651, and because, given the likelihood that a layman would conflate legal "fees" with other litigation "costs," the possibility that "substantial numbers of potential clients would be . . . misled [was] hardly a speculative one," *id.* at 652; *see also, e.g.*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1340 (2010) (law firm required to disclose that it functioned as a debt-relief agency, which "entail[ed] only an accurate statement identifying the advertiser's legal status and the character of the assistance provided").

In contrast, courts have found that disclosure requirements are "unjustified and unduly burdensome" where they limit the ability of a business to convey its own message or where the possibility that the disclosures will prevent consumer confusion is only speculative. Thus, in *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136 (1994), the Court invalidated a requirement that any use of a designation as an accounting specialist be accompanied by a comprehensive disclaimer. The Court reasoned that the length of the disclaimer "effectively rule[d] out notation of the 'specialist' designation on a business card or letterhead, or in a yellow pages listing"; and yet the state had failed to identify "any harm that is potentially real, not purely hypothetical." *Id.* at 146-47. Likewise, in *International Dairy Foods Association v. Boggs*, 622 F.3d 628 (6th Cir. 2010), the court invalidated an Ohio law that required milk processors who advertise that their milk comes from cows not supplemented with rbST to include a contiguous additional statement that "[t]he FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows." *Id.* at 634. The court reasoned that, although the risk of consumer confusion addressed by the disclosure requirement *in general* "[wa]s not speculative," the state had identified nothing more than an agency director's "anecdotal experience" to suggest that the disclosure had to be contiguous with the initial statement regarding rbST-free production in order to prevent such confusion. *Id.* at 642-43; *see also Entm't Software Ass'n v. Blagojevich*, 404 F. Supp. 2d 1051, 1081-82 & n.12 (N.D. Ill. 2005) (invalidating video game warning requirements because the state "offered no evidence that there is any actual confusion or deception of parents or children" and because the disclosure requirements were "far more extensive than the Ohio Disciplinary Rule considered in *Zauderer*"), *aff'd*, 469 F.3d 641 (7th Cir. 2006).

Here, when the benefits of the Rule are balanced against the burdens imposed on Plaintiffs and other manufacturers, the Rule plainly is "unjustified and unduly burdensome." *First*, on the benefits side of the balance, FDA's RIA, the FDA Study, and the Viscusi and Maness Reports all

confirm that the expected impact of the Rule on smoking rates is "in general not statistically distinguishable from zero." 76 Fed. Reg. at 36,776. *See supra* at 8. This is all the more devastating because, as explained by Drs. Viscusi and Maness, the RIA and the FDA Study contain numerous flaws that artificially *inflate* the benefits of the Rule. *See supra* at 8-10.

Second, on the other side of the balance, the Rule confiscates the most prominent portion of Plaintiffs' packaging for disturbing graphic images designed to encourage consumers *not* to purchase Plaintiffs' lawful products. In contrast, Plaintiffs' marketing message is limited to the much less prominent and visible portion of the packaging, the bottom half. These shocking graphics must be duplicatively displayed on *both* sides of the packaging. Given the limited space available to Plaintiffs on their packaging, some marketing messages may have to be abandoned altogether.[22] The graphics thus overwhelm and drown out Plaintiffs' own marketing messages.

Indeed, an exhibit provided by FDA on its webpage to depict a sales counter with the new warnings drives this point home. Under applicable state and federal law, tobacco products generally must be displayed several feet behind a sales counter. *See, e.g.*, 21 C.F.R. § 1140.16(c). As a result, it will be nearly impossible for consumers at retail to see Plaintiffs' marketing messages on their packages.[23] Instead, the only thing that consumers will likely see at retail is *the Government's* graphic message, as demonstrated on FDA's own webpage:[24]

[22] For example, the back of a package of *Camel* filter cigarettes currently states that "[a] master-crafted blend of only the finest hand-picked Samsun & Izmir Turkish tobaccos with robust domestic tobacco blend creates Camel's distinctive flavor and world-class smoothness." Dunham Decl. ¶ 28. If 50% of both principal display panels of packaging must be dedicated to the new warning, then, "[a]s a practical matter, that same message cannot be conveyed … because the type face would have to be made much smaller." *Id.* This is vividly demonstrated in the images reproduced in paragraph 28 of the Dunham Declaration.

[23] *See* Dunham Decl. ¶ 29 ("Merchandising fixtures are typically several feet behind a sales counter, and if our packaging has 50% less space for conveying messages, and [is] thus viewed from several feet away, words quickly becomes illegible . . . ."); Comment Letter, Exhibit D, Declaration of Timothy Jones ¶ 31 ("[U]nder the new restrictions imposed by the Act, adult consumers will not be able to see the information on our packaging at retail. . . . [The Act's] new restrictions will, as a practical matter, mean that all of the information that distinguishes our products from our competitors' products will not be visible to the adult consumer before he or she makes a purchase.").

[24] *Available at* http://www.fda.gov/TobaccoProducts/Labeling/CigaretteWarningLabels/ucm259862.htm.

These burdens, moreover, are magnified by the fact that Plaintiffs' packaging and advertising (through direct mail, at retail points of sale, and in magazines) are the most important remaining avenues that Plaintiffs have to communicate with adult tobacco consumers. *See supra* at 3. The Rule eviscerates both by confiscating (1) the top half of both sides of packaging for the graphic warnings while relegating Plaintiffs' marketing message to the bottom half, and (2) the top fifth of advertising for the color graphics while limiting Plaintiffs' advertising to black and white text. *See supra* at 4-6. Where, as here, commercial speakers have "few avenues of communication" with consumers, restrictions on those few avenues "place a greater, not lesser, burden on [their] speech." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564-65 (2001); *see also Linmark Assocs. v. Twp. of Willingboro*, 431 U.S. 85, 93 (1977) (invalidating ban on house "for sale" signs where the alternative avenues of speech existed only "in theory").

In sum, the Rule fails to offer any benefit "that is potentially real, not purely hypothetical," and, at the same time, imposes severe burdens on Plaintiffs' free speech rights by "effectively rul[ing] out" crucial avenues for their own speech. *Ibanez*, 512 U.S. at 146. It is, therefore, the epitome of an "unjustified or unduly burdensome" restriction on free speech. *Zauderer*, 471 U.S. at 651. Indeed, if the Rule does not exceed the limitations of *Zauderer*, then it is difficult to imagine what types of tobacco-product warnings would.

C. The Rule Also Impermissibly Burdens Plaintiffs' Commercial Speech Under *Central Hudson*.

Finally, the Rule also unconstitutionally burdens Plaintiffs' First Amendment right to disseminate their own commercial speech. In particular, by prohibiting Plaintiffs from using the top 50% of their packages and the top 20% of their advertisements to disseminate their own commercial messages, and instead requiring that space to be dedicated to the Government's graphic warnings, the Rule is comparable to (though more burdensome than) a requirement that the top half of packages and top fifth of advertisements be left blank. Indeed, displacing and drowning out tobacco companies' own speech appears to have been an additional goal behind the Rule; as Secretary Sebelius explained, the graphic warnings effectively "rebrand[] our cigarette packs." *See* Press Briefing, *supra* note 2. The Rule therefore must also satisfy the First Amendment standard for restrictions on commercial speech under *Central Hudson*, pursuant to which the Government bears the burden of showing that (1) the Government's asserted interest is substantial, (2) the Rule directly advances that interest, and (3) the Rule is not more extensive than is necessary to serve that interest. *See Lorillard*, 533 U.S. 525, 566 (2001); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002). The Rule decisively fails this test.

First, although FDA has a substantial interest in preventing misleading commercial speech, it does *not* have a legitimate interest in preventing Plaintiffs from marketing their lawful product simply because it wishes to reduce smoking and fears that such marketing may be effective. As

Justice Blackmun stated in *Central Hudson*:

> Even though 'commercial' speech is involved, [this kind of restriction] strikes at the heart of the First Amendment. This is because it is a covert attempt by the State to manipulate the choices of its citizens, not by persuasion or direct regulation, but by depriving the public of the information needed to make a free choice.
>
> . . . [The] State's policy choices are insulated from the visibility and scrutiny that direct regulation would entail and the conduct of citizens is molded by the information that government chooses to give them.

447 U.S. at 574-575, (Blackmun, J., concurring in judgment). The Rule at issue here is likewise designed to manipulate the choices of adult citizens. As discussed, the graphic warnings are not intended to cure an information deficit, but rather, as Secretary Sebelius explained, to "rebrand[] our cigarette packs" in order to "change the consumer response to a package of cigarettes." *See* Press Briefing, *supra* note 2.

The burden on Plaintiffs' speech is magnified by the separate statutory requirement that Plaintiffs' own advertising be limited to black and white text. As a result, Plaintiffs' advertisements will be dominated by the emotionally-charged graphic warning, which must occupy the top fifth of all advertisements. Indeed, as a result of this one-two punch, the primary message transmitted through Plaintiffs' advertisements will be the *Government*'s anti-smoking message. The self-evident purpose of these dual requirements is to simultaneously magnify the Government's anti-smoking message and drown out Plaintiffs' marketing. But as the Supreme Court recently reiterated, the First Amendment bars the Government from furthering its policy goals by "burden[ing] the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 2011 WL 2472796, at *17.

Second, even if the Rule were plausibly targeted at preventing consumer deception, as opposed to manipulating consumers, it would still not "directly and materially advance" that interest, *Rubin*, 514 U.S. at 488. As explained above, FDA has effectively conceded that the impact of the Rule on smoking prevalence will be negligible to non-existent. Hence, the purported benefits are impermissibly based on "mere conjecture." *Nixon v. Shrink Mo. Gov't PAC*, 528 U.S. 377, 392 (2000).

Finally, the Rule is clearly "more extensive than is necessary to serve" a governmental interest in preventing misleading commercial speech, *Thompson*, 535 U.S. at 367, going well beyond anything reasonably necessary to inform the public of the health risks of smoking and ignoring numerous and obvious less restrictive alternatives. *See supra* at 28-30. Indeed, if the Rule is permissible, there is no end to what the Government could do to control the behavior of its citizens to prevent lawful but, in the Government's view, improper conduct. For example, according to a recent Rand Corporation study, obesity "is linked to a big increase in chronic health conditions and significantly higher health expenditures [and] affects more people than smoking, heavy drinking, or poverty."[25] If the Rule is permissible, the same would be true of like warnings on fatty or high-calorie foods, or any other lawful product that the Government frowns upon. The Supreme Court, however, has made crystal clear that "the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, non-misleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or burden its messengers." *Sorrell*, 2011 WL 2472797, at *16. That is precisely what the Rule at issue here does, not only in practical effect, but by design. It is irreconcilable with the First Amendment.

II. THE RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT.

In addition to violating core constitutional principles, the Rule also violates the APA. *First*, the Rule is a paradigm example of arbitrary and capricious agency action. *Second*, FDA also failed to disclose information critical to a full and fair evaluation of the Rule.

A. FDA Acted Arbitrarily And Capriciously.

The APA directs courts to set aside agency action that is "arbitrary and capricious." 5 U.S.C. § 706(2)(A). In order to satisfy this review, an agency "must examine the relevant data and articulate

[25] Rand Corporation, "The Health Risks of Obesity: Worse Than Smoking, Drinking, or Poverty" available at http://www.rand.org/content/dam/rand/pubs/research_briefs/2005/RB4549.pdf.

a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Arent v. Shalala*, 70 F.3d 610, 616 (D.C. Cir. 1995) (internal quotation marks omitted). This mandate gives rise to at least four subsidiary requirements, each of which FDA violated, and each of which independently requires vacatur of the Rule.

First, a rule is arbitrary and capricious where an agency's analysis in support of the rule (or its rejection of alternatives to the rule) is illogical. *See Public Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209 (D.C. Cir. 2004). In *Public Citizen*, the court invalidated a rule governing driving times by long-haul truck drivers in part because the agency's analysis in support of the rule was internally contradictory. The agency had increased from 10 to 11 the number of consecutive hours during which truck drivers could stay *on duty* each day and also had increased the number of hours a driver was required to be *off duty* from 8 to 10 hours. 374 F.3d at 1218. But although the agency had counted benefits from the additional rest time given drivers in the form of fewer accidents, it had assumed that the increase in on-duty time would not increase the number of accidents "because, the agency said, it did not have sufficient data on the magnitude of such effects." *Id.* at 1219. By predicting benefits from the additional rest time yet excluding the costs of longer drive time, the court reasoned, the agency had "assume[d] away the exact effect that the agency attempted to use . . . to justify" the regulation. *Id.*

Similarly here, FDA grounded the Rule on scientifically unjustified and "highly uncertain" estimates of the Rule's benefits, 76 Fed. Reg. at 36,720, but *refused* to consider costs such as increases in illicit cigarette sales, lost jobs, and lost profits for tobacco farmers, because estimates of those costs would be uncertain. *See supra* note 10. Indeed, FDA ignored these costs despite the possibility of estimating them through the same methodology it used to estimate the Rule's benefits. *See, e.g.*, Maness Report at 29 ("The Canadian experience is a useful guide for measuring potential agricultural losses from the [FDA's] rule."). This is precisely the sort of double standard that the D.C. Circuit in *Public Citizen* held to be arbitrary and capricious. *See* 374 F.3d at 1219.

Second, an agency acts arbitrarily and capriciously when it justifies a regulation on grounds that are implausible or are otherwise unsupported by the regulatory record. Thus, in *Public Citizen*, the court additionally found that the agency had acted arbitrarily and capriciously because, "[q]uite apart from the circularity of the agency's explanation," in light of the many studies correlating longer drive times with higher accident rates, "the model's assumption that time-on-task effects are nil [wa]s implausible." *Id*; *see also Nat'l Nutritional Food Ass'n v. Weinberger*, 512 F.2d 688, 701 (D.C. Cir. 1975) ("Where the agency's finding is not sustainable on the administrative record made, then the …decision must be vacated and the matter remanded to (the agency) for further consideration."); *id.* at 705 (Lumbard, J. concurring) ("A district judge should carefully examine the information that was before the agency to see if it gives adequate and substantive support to the agency's position. . . . [A] court should not hesitate to overturn an agency's action if it is not fairly supported by the evidence before the agency.").

Here, FDA expressly states that the purpose of the Rule is to improve public health by convincing "smokers [to] reduce their smoking, make an attempt to quit, or quit altogether." 76 Fed. Reg. at 36,634, and purports to measure the benefits of the rule in terms of reductions in health care costs occasioned by decreases in smoking, *id.* at 36,707. Yet the administrative record is devoid of evidence demonstrating that the chosen warnings will significantly advance that goal. As explained above, *see supra* at 7-14, the RIA and FDA Study systematically overstate benefits and understate costs, yet still are unable to conclude with any certainty that the Rule will result in any material benefits.

Third, "[a] long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently." *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) (collecting cases); *see also Airmark Corp. v. Fed. Aviation Admin.*, 758 F.2d 685, 692 (D.C. Cir. 1985) ("Elementary even-handedness requires that if [a particular standard] must be met by one petitioner, then [the same standard] must be met by the

next."). In the final Rule, however, FDA applied different standards of analysis to comments supporting the Rule and comments opposing the Rule. For example, FDA rejected comments that the alarming nature of the graphic warnings could in fact increase cigarette use by causing consumers to avoid the warnings or increasing the appeal of cigarettes to some young people, stating that such comments "did not provide persuasive scientific evidence." *Id.* at 36,634. On the other hand, even while acknowledging that comments from certain "academics, a nonprofit organization and a prevention specialist" had limited utility because they failed to provide "raw data" and "statistical analyses," FDA nevertheless used such comments to support its conclusions and choice of graphic warnings. *See* 76 Fed. Reg. at 36,645. Indeed, one study cited by FDA could only conclude that "emotional associations to smoking *appear to be* powerful predictors of smoking behavior and *may well be causally implicated* in efforts to either stop or start smoking," yet FDA still used this study as "additional support" for the agency's conclusions. *Id.* at 36,642 (emphasis added).

Fourth, a rule is "arbitrary and capricious if the agency" ignores an alternative regulatory approach that is "neither frivolous nor out of bounds." *Chamber of Commerce v. SEC*, 412 F.3d 133, 144-45 (D.C. Cir. 2005) (invalidating SEC rule where SEC "fail[ed] adequately to consider a proposed alternative" that "the Commission . . . had an obligation to consider" because it "was neither frivolous nor out of bounds and"). Here too, as previously noted, *see supra* at 28-30, some of the Plaintiffs provided comments to FDA describing the substantial economic and constitutional burdens the Rule would place on them and urging FDA to mitigate these burdens by considering a number of alternative regulatory approaches. Comment Letter at 15-16, 18-19. The Rule, however, offers no rational explanation for rejecting these numerous alternatives.

In sum, as the D.C. Circuit recently explained when invalidating a regulation on grounds equally applicable here, "the [agency] inconsistently and opportunistically framed the costs and benefits of the rule; failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to

respond to substantial problems raised by commenters." *Bus. Roundtable & Chamber of Commerce of the United States v. SEC*, 2011 U.S. App. LEXIS 14988, at *8-9 (D.C. Cir. July 22, 2011). Such blithe imposition of substantial burdens, with no attempt to justify them based on any corresponding policy need, is the epitome of arbitrary and capricious agency action.

B. FDA Failed To Provide A Meaningful Opportunity To Comment.

Under the APA, FDA is obligated to "provide the public with a meaningful opportunity to comment on" new regulations prior to their publication. *Hall v. EPA*, 273 F.3d 1146, 1162-63 (9th Cir. 2001) (citing 5 U.S.C. § 553(b)(3)). "In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.'" *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982). Such disclosures ensure a meaningful "exchange of views, information, and criticism between interested persons and the agency." *Home Box Office, Inc. v. F.C.C.*, 567 F.2d 9, 35 (D.C. Cir. 1977).

For example, in *American Radio Relay League, Inc. v. FCC*, the Court invalidated an FCC regulation because the agency had "redact[ed] studies on which it relied in promulgating the rule and failed to provide a reasoned explanation for its choice of the extrapolation factor for measuring [certain power line] emissions." 524 F.3d 227, 231 (D.C. Cir. 2008). The agency's failure to disclose violated the notice requirements of the APA, the Court explained, because "[i]t is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, to a critical degree, is known only to the agency." *Id.* at 237 (internal quotation marks omitted). Thus, "[w]here . . . an agency's determination is based upon a complex mix of controversial and uncommented upon data and calculations," the court concluded, an agency may not "cherry-pick a study on which it has chosen to rely in part." *Id.*

Here, as Dr. Viscusi explains, numerous portions of the Proposed Rule were based on unspecified and unidentified information, without which the public was denied "a meaningful

opportunity to comment on the proposed provisions." *Hall*, 273 F.3d at 1162 (internal quotation marks omitted). For example, despite previous comments by Dr. Viscusi noting the importance of disclosing FDA's process for selecting warning text and graphics, the FDA Study "neglected to describe those processes in meaningful detail." Viscusi Report at 37. "The lack of this documentation undermine[d] the ability to offer comments on those judgments and processes." *Id.* Indeed, in the Final Rule, FDA described a previously undisclosed approach, under which it relied primarily on the "salience" effects of the graphics rather than the numerous other issues that the study itself describes as its main focus. 76 Fed. Reg. at 36,639.

Likewise, FDA "failed to provide sufficient information to make it possible for an outside reviewer to evaluate its methodology and conclusions," including "even basic support for its calculations of important elements of its cost-benefit assessment." Maness Report at 5. For example, although FDA estimated the impact of the Rule based on a regression analyses of smoking rates and excise taxes in Canada, it has failed to disclose key technical data and assumptions it used in running these regressions. *See* 75 Fed. Reg. at 69,543; 76 Fed. Reg. at 36,755.[26] Due to FDA's failure to disclose its technical data and assumptions, Dr. Maness was unable to replicate the results of FDA's cost-benefit analysis, which in turn made it "impossible to fully assess and comment on [FDA's]conclusions." Maness Report at 5.[27]

Because an "integral" component of notice-and-comment rulemaking is "the agency's duty to identify and make available technical studies and data that it has employed in reaching decisions to propose particular rules," this failure to disclose "the technical basis for [FDA's] proposed rule in time to allow for meaningful commentary" constitutes "serious procedural error." *Owner-Operator*

[26] For example, FDA reports that it estimated the pre-2001 smoking trend in Canada based on 7 observations of Canadian data, 76 Fed. Reg. at 36,755, table 42, yet it reports only 6 of these observations, 76 Fed. Reg. 36,721, table 4. Moreover, although FDA used observations that span a two-year period (*e.g.*, 1994-1995), it did not disclose how these observations were included in the trend variable, (*i.e.*, whether the variable was used twice, for both 1994, 1995, or treated as an observation at year 1994.5, or some third approach).

[27] *Cf.* 76 Fed. Reg. at 36,645 (noting that comments that "did not [provide] access to the raw data or to all the statistical analyses for the studies discussed" were of "limited . . . utility").

Ind. Drivers Ass'n. v. Federal Motor Carrier Safety Admin., 494 F.3d 188, 199, 201 (D.C. Cir. 2007) (holding that because the agency's operator-fatigue model was "unquestionably among the most critical factual material that was used to support the agency's position," the "failure to provide an opportunity for comment on the model's methodology therefore constitute[d] a violation of the APA's notice-and-comment requirements").

This failure is particularly troublesome given that the information FDA *has* disclosed "appear[s] to contain information in tension with the [agency's] conclusion." *Am. Radio Relay League*, 524 F.3d at 238. The undisclosed information therefore could "contain evidence that could call into question the [agency's] decision to promulgate the rule." *Id.* at 239. Indeed, the partial disclosure provided by FDA does just that; as described above, *supra* note 9, if taken at face value, FDA's own model suggests the possibility that factors besides graphic warnings had a larger impact on smoking rates in Canada, and the warnings, in fact, caused smoking rates in Canada to *increase.* Similarly, had FDA fully disclosed its calculations, Dr. Maness and other experts may have been able to adjust the agency's flawed model to account for confounding variables such as increased cigarette prices, which likely would have reinforced the evidence that the Rule will in fact have no meaningful impact on smoking trends. FDA's lack of disclosure has instead left the public unable to assess fully the agency's reasoning and precluded a meaningful "exchange of views, information, and criticism between interested persons and the agency." *Home Box Office, Inc.*, 567 F.2d at 35.

Accordingly, in addition to all of the other flaws described herein, FDA's failure to disclose data and other information critical to a full and fair assessment of its decision to promulgate the Rule also violates the APA.

III. UNDER THE ACT, NO CHANGES TO CIGARETTE PACKAGING OR ADVERTISING MAY TAKE EFFECT UNTIL 15 MONTHS AFTER THE ISSUANCE OF A *VALID* RULE.

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).

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 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)).

Although Plaintiffs in this action do not challenge the legality of these requirements, the effective dates of these requirements are dependent on the validity of the Rule. 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. Indeed, prior drafts of the Act provided that the new textual warnings and Related Requirements would become effective for all tobacco products, including cigarettes, one year after enactment of the Act. *See* H.R.1256, 111th Cong. §§ 103(q)(5), 201(b), 301 (Apr. 2, 2009). Yet, shortly before it passed the Act, Congress amended it to provide, as described above, that the new textual warnings and Related Requirements would become effective for cigarette packaging and advertising (*i.e.*, the packaging and advertising affected by the Rule) on the same date as the effective date of the Rule. The self-evident purpose behind this amendment was to ensure that all of the Act's changes to cigarette packaging and advertising would be implemented together.

In light of this plain congressional purpose, the Act must be read to tie the effective dates of the textual warnings and Related Requirements to the issuance of a *substantively and procedurally valid* Rule. Such an interpretation is necessary to effectuate congressional intent. If the Court were to invalidate the Rule in whole or in part, yet construe the new textual warnings or Related Requirements to become effective 15 months after the issuance of the *invalid* Rule, Plaintiffs would be forced to overhaul their packaging once to implement the textual warnings (to the extent possible without a valid Rule) and the Related Requirements, and a second time to implement any later regulation issued to replace the invalid Rule. Indeed, a reading that would allow the textual warnings and Related Requirements to be triggered by an invalid Rule could permit anomalous results. For example, had FDA published the Rule one week after the Act without any notice or opportunity for comment, and had the Rule been promptly invalidated, it would be absurd to conclude that such a Rule would trigger the effective dates of the textual warnings and Related Requirements and deprive tobacco product manufacturers of the single implementation period intended by Congress.

CONCLUSION

For the foregoing reasons, Plaintiffs request that this Court grant Plaintiffs' motion for summary judgment; declare that the Rule violates the First Amendment and violates the APA; and enjoin Defendants from enforcing the Rule against Plaintiffs.

Respectfully Submitted,

Dated: August 19, 2011

/s/ Noel J. Francisco

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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 PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT AND PERMANENT INJUNCTION

For the reasons set forth in Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment, and based on the Court's review of both parties' arguments and the agency record,

it is hereby ORDERED that Plaintiffs' Motion For Summary Judgment is GRANTED. The Court hereby:

1. DECLARES that the Regulation published at 76 Fed. Reg. 36,628 (June 22, 2011) violates the First Amendment and the APA, 5 U.S.C. §§ 553(b)(3), 706(2)(A) and SETS ASIDE said Regulation;

2. PERMANENTLY ENJOINS, until 15 months following the issuance of new regulations implementing Section 201(a) of the Tobacco Control Act that are substantively and

procedurally valid and permissible under the United States Constitution and federal law, Defendants from enforcing against Plaintiffs in this action the new textual and graphic warnings required by Section 201(a) of the Tobacco Control Act;

3. PERMANENTLY ENJOINS, until 15 months following the issuance of new regulations implementing Section 201(a) of the Tobacco Control Act that are substantively and procedurally valid and permissible under the United States Constitution and federal law, Defendants from enforcing against Plaintiffs in this action the following statutory provisions, which impose the stated labeling requirements:

    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).

4. DECLARES that Plaintiffs in this action are permitted to continue using their current cigarette packaging and advertising until 15 months following the issuance of new regulations by Defendants implementing Section 201(a) of the Tobacco Control Act that are substantively and procedurally valid and permissible under the United States Constitution and federal law

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

_____
Hon. Richard J. Leon
United States District Judge